Women's Health Initiative
Clinical Trial and Observational Study

Semi-Annual Progress Report
March 1, 2001 to August 31, 2001

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WHI Semi-Annual Progress Report

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Executive Summary

This report, summarizing data accumulated through August 31, 2001, presents the current status of the three clinical trial (CT) components and the Observational Study (OS) of the Women's Health Initiative (WHI). The primary areas for this report are adherence to the interventions, completeness of follow-up, safety, and event rates by age and ethnicity for each component.

Final recruitment numbers for the CT and OS have been updated since the previous report. A more thorough search of the database revealed several duplicate enrollments. In the CT, two women were randomized at two different clinical centers. Removing these duplicate enrollments resulted in a reduction by one in the final enrollment for each CT component. Several OS women were enrolled in multiple sites and a limited number of other participants have such limited baseline data that they cannot be effectively included in subsequent analyses. These are now excluded from our OS analysis cohort. All numbers reported reflect these changes.

The Hormone Replacement Therapy (HRT) component completed accrual with 27,347 women randomized, including nearly 40% who had previously experienced a hysterectomy. The average follow-up on these women is just about 4.6 years. Overall drop-out rates, now with estimates available through the seventh year, continue to be somewhat higher than design assumptions as are "drop-in" rates. Analyses of intermediate effects, including blood biomarker analyses and bone density are provided by hysterectomy status and race/ethnicity. Vital status is known within the last 18 months for all but 944 women (3.5%). We lack recent follow-up on another 29 (0.1%) and 2.3% are known to be deceased. The current event rates for CHD, breast cancer, colorectal cancer, and hip fractures are approximately 65%, 75%, 80%, and 35%, respectively, of projected rates. Power calculations using updated parameter estimates for all key design elements other than treatment effect are provided.

The Dietary Modification (DM) component randomized 48,836 women. Intervention adherence is monitored by the difference between the Intervention and Control arms in Food Frequency Questionnaire (FFQ) percent energy from fat (C-I). Studywide, the FFQ mean difference between Intervention and Control women is 10.9% energy from fat at AV-1 decreasing to 8.1% at AV-7. The corresponding design assumptions for the C-I comparisons were 13% at year 1, diminishing to 0.25% per year though adequate power can be maintained as long as this difference remains at or above 10%. For fruit and vegetable intake, the mean difference between the arms of the trial remains consistently in excess of 1 more serving per day for Intervention vs. Control women. Compared to Control women, Intervention women consumed almost 1 more serving per day of grains at AV-1, decreasing to one-half serving at AV-7. Currently 3.3% of the DM participants are lost-to-follow-up or have stopped follow-up, 0.1% lack recent follow-up, and 2.0% of the participants are known to be deceased. The average follow-up time for DM women is approximately 4.7 years. The current incidence rates of breast cancer, colorectal cancer, and CHD are approximately 105%, 70%, and 60%, respectively, of what was assumed in the study design. Event rates by age and race/ethnicity are presented for all monitored outcomes. Updated power calculations are included.

The Calcium and Vitamin D (CaD) component randomized 36,282 women previously recruited to the trial. Adherence to CaD supplements, defined as known consumption of 80% or more of the

prescribed study pills, has remained steady since the last report and is now 57%-63%, though still lower than desirable. Follow-up rates for CaD participants are better than for the other CT components; as only 1.7% of participants are lost-to-follow-up or have stopped follow-up, and 1.5% of the participants are known to be deceased. Virtually all of the remaining participants have completed a *Form 33 – Medical History Update* in the last 18 months. Descriptive statistics for the intermediate outcomes of blood analyses and bone mineral density measures are presented overall and by race/ethnicity. With an average follow-up time of 43 months, the current rates of hip fractures, invasive breast cancer, and colorectal cancer are approximately 40%, 105%, and 75%, respectively, of what was assumed in the study design. Event rates by age and race/ethnicity are presented for all monitored outcomes. Power calculations for this component have been updated with current estimates of design parameters other than treatment effect.

The Observational Study analytic cohort is comprised of 93,676 women. Follow-up rates suggest strong retention overall as only 3.0% are considered lost-to-follow-up or have stopped follow-up, and <5% have not provided outcomes data within the last year. Responses to mailings are generally high (>93%). Approximately 82% of the 3-year clinic visits due have been conducted, as judged by task completeness. Event rates by age and racial/ethnic categories are presented for all adjudicated outcomes.

Additional information on the timeliness and quality of outcomes ascertainment is provided. Some corrections of outcomes reporting are included in this report. The definition of CHD deaths, previously discussed for HRT, was corrected for all trial components and all related summary measures (e.g. CHD, coronary disease, cardiovascular disease). A small number of stroke deaths which had previously been reported only as deaths and not incident events, are now included in the specific incident event categories as well as their related summary events. We note that the first search of the National Death Index (NDI) was conducted and the results included in these tables. From this, 53 participant deaths were ascertained, of which 26 have not yet been reported by traditional means.

Finally, a summary of clinical center performance and listings of publications and ancillary study activities is provided.

1. Preliminary Remarks

This report documents study activities of the Women's Health Initiative (WHI) Clinical Trial (CT) and Observational Study (OS) through August 31, 2001. Topics include intervention adherence, follow-up, safety, outcomes, study power, and specialized scientific efforts. Updates are provided for each study component separately with a separate section on outcomes devoted to data quality, processing and timeliness issues.

During the past 6 months, major milestones, emphases, and efforts have included:

- Finalizing the membership in each of the study cohorts after central review of the data and removal of duplicate enrollments and a few individuals with extremely sparse baseline data.
- Provision of updated information to HRT trial participants of a continuing elevation in the risk of cardiovascular disease.
- Significant progress on the WHI substudy to examine CVD biomarkers in the HRT trial.
- Continuing efforts of the "Targeted Message Campaign," an initiative to support the DM Intervention.
- Development of the next DM intervention initiative referred to as the Personalized Evaluation of Fat Intake (PEFI) for implementation in mid 2002.
- Implementation of central adjudication for strokes in HRT women and modification of central adjudication of cardiovascular disease, focussing on HRT women and streamlining the effort for other study components.
- Completion of our first search of the National Death Index.
- Initiation of working groups to plan for close-out activities and options for extended follow-up.

All reports summarize Clinical Center (CC) data provided to the CCC by August 31, 2001. All data presented are derived from WHILMA, the study database. Data managed in WHILMA are those defined by standardized data collection procedures and instruments (see *WHI Manuals, Vol. 2 - Procedures and Vol. 3 - Forms*).

Clinical Center locations and Principal Investigators (PI) are listed in Table 1.1. We wish to acknowledge some changes in the leadership of these centers. Larry Phillips has assumed the role of PI at the Atlanta CC, replacing Nelson Watts, who has left Emory for a position at the University of Cincinnati. Marjorie Gass is replacing James Liu as PI of the Cincinnati CC. Dr. Liu will become a consultant at that site. Karen Margolis is the new PI for Minnesota, taking over for Richard Grimm, who continues as an investigator. Electra Paskett is leaving Wake Forest (Bowman Gray) for a position in Ohio and will become an investigator at the Columbus clinic. A new PI for the Bowman-Gray CC has not yet been named.

We wish to remember Dr. Carolyn Clifford, a Project Officer from NCI who passed away on May 31, 2001. Dr. Clifford was an active contributor in the planning phase of WHI and served as a valuable resource for cancer and dietary issues.

Finally, we wish to acknowledge the contributions of Dr. Richard Carleton, Co-PI of the Pawtucket, Rhode Island who died on September 12, 2001. Dr. Carleton played an active role in the local clinic and in the study nationwide as a physician adjudicator, M&M committee member and general supporter for the study. His voice and his efforts will be deeply missed.

Table 1.1
Database Abbreviations for WHI CCs

Abbreviation	CC Institution and Location	Principal Investigator
ATLANTA	Emory University Atlanta (Decatur), Georgia	Larry Phillips, MD
BIRMING	University of Alabama at Birmingham Birmingham, Alabama	Cora Lewis, MD MSPH
BOWMAN	Bowman Gray School of Medicine Winston-Salem (Greensboro), North Carolina	Electra Paskett, PhD
BRIGHAM	Brigham and Women's Hospital Boston (Chestnut Hill), Massachusetts	Joann Manson, MD DrPH
BUFFALO	State University of New York, Buffalo Buffalo, New York	Maurizio Trevisan, MD MS
CHAPHILL	University of North Carolina at Chapel Hill Chapel Hill, North Carolina	Gerardo Heiss, MD MPH
CHICAGO	Northwestern University Chicago and Evanston, Illinois	Linda Van Horn, PhD RD
CHI-RUSH	Rush Presbyterian- St. Luke's Medical Center Chicago, Illinois	Henry Black, MD
CINCINNA	University of Cincinnati Cincinnati, Ohio	Marjorie Gass, MD
COLUMBUS	Ohio State University Columbus, Ohio	Rebecca Jackson, MD
DETROIT	Wayne State University Detroit, Michigan	Susan Hendrix, DO
GAINESVI	University of Florida Gainesville and Jacksonville, Florida	Marian Limacher, MD
GWU-DC	George Washington University Washington, DC	Judith Hsia, MD
HONOLULU	University of Hawaii Honolulu, Hawaii	David Curb, MD
HOUSTON	Baylor College of Medicine Houston, Texas	Jennifer Hays, PhD
IOWACITY	University of Iowa Iowa City and Bettendorf, Iowa	Robert Wallace, MD

Table 1.1 (continued)
Database Abbreviations for WHI CCs

Abbreviation	CC Institution and Location	Principal Investigator
IRVINE	University of California, Irvine Irvine, California	Allan Hubbell, MD
LA	University of California, Los Angeles Los Angeles, California	Howard Judd, MD
LAJOLLA	University of California, San Diego La Jolla and Chula Vista, California	Robert Langer, MD MPH
MADISON	University of Wisconsin Madison, Wisconsin	Catherine Allen, PhD
MEDLAN	Medlantic Research Institute Washington, D.C.	Barbara Howard, PhD
MEMPHIS	University of Tennessee Memphis, Tennessee	Karen Johnson, MD
MIAMI	University of Miami Miami, Florida	Mary-Jo O'Sullivan, MD
MILWAUKE	Medical College of Wisconsin Milwaukee, Wisconsin	Jane Morley Kotchen MD MPH
MINNEAPO	University of Minnesota Minneapolis, Minnesota	Karen Margolis, MD
NEVADA	University of Nevada Reno, Nevada	Robert Brunner, PhD
NEWARK	University of Medicine and Dentistry Newark, New Jersey	Norman Lasser, MD PhD
NY-CITY	Albert Einstein College of Medicine Bronx, New York	Sylvia Wassertheil-Smoller, PhD
OAKLAND	Kaiser Foundation Research Institute Oakland, California	Bette Caan, PhD
PAWTUCK	Memorial Hospital of Rhode Island Pawtucket, Rhode Island	Annlouise Assaf, PhD
PITTSBUR	University of Pittsburgh Pittsburgh, Pennsylvania	Lewis Kuller, MD DrPH
PORTLAND	Kaiser Foundation Research Institute Portland, Oregon	Cheryl Ritenbaugh, PhD

Table 1.1 (continued)
Database Abbreviations for WHI CCs

Abbreviation	CC Institution and Location	Principal Investigator
SANANTON	University of Texas San Antonio, Texas	Robert Schenken, MD
SEATTLE	Fred Hutchinson Cancer Research Center Seattle, Washington	Shirley Beresford, PhD
STANFORD	Stanford University San Jose, California	Marcia Stefanick, PhD
STONYBRK	Research Foundation of SUNY, Stony Brook Stony Brook, NY	Dorothy Lane, MD MPH
TORRANCE	University of California, Los Angeles Torrance, California	Rowan Chlebowski, MD PhD
TUCSON	University of Arizona Tucson and Phoenix, Arizona	Tamsen Bassford, MD
UCDAVIS	University of California, Davis Sacramento, California	John Robbins, MD
WORCESTR	University of Massachusetts Worcester, Massachusetts	Judith Ockene, PhD

2. HRT Component

2.1 Recruitment

27,347 women were randomized into the HRT component (99.4% of goal). Of these, 10,739 women had a prior hysterectomy (39%) and were randomized to either unopposed estrogen (ERT) or placebo in equal proportions. The remaining 16,608 women with an intact uterus were randomized to combined estrogen/progestin (PERT) or its placebo, again in equal proportions for most of the recruitment period. *Table 2.1* documents the age and racial/ethnic distribution of this population.

2.2 Adherence

Adherence to medications is determined at clinic visits by weighing returned bottles, if available, or by self-report in the small proportion of women with missed pill collection. *Table 2.2 – HRT Adherence Summary* gives descriptive data on all women who are considered due for each contact by treatment arm. For visits that were complete in the last report, only summaries across arms are provided. For stopping intervention and medication rates, the 331 who were moved from ERT to PERT in 1995 were excluded. The adherence summary in the final column is defined as the number of women known to have consumed more than 80% of their assigned HRT pills during that interval as a proportion of the number randomized and eligible for this visit; women not providing adherence data are considered non-adherent. The adherence summaries for the last six annual visits (AV-2 to AV-7) are 69%, 63%, 59%, 55%, 53%, and 49% respectively, essentially unchanged in the last 6 months. In comparing hysterectomy strata, there is continuing evidence of somewhat better adherence in women with a uterus through AV-6.

Figure 2.1 presents the secular trends in adherence rates for each visit type for the entire HRT cohort and by hysterectomy status. These graphs suggest no sharp changes in adherence with time and, in particular, no sense of a strong negative response to our most recent update on cardiovascular effects. We note, however that the earliest data presented for each visit type is often significantly lower than subsequent observations, suggesting that the cohort of early enrollees maybe somewhat different in their adherence, particularly in participants with a uterus.

Table 2.3 presents drop-in and drop-out rates and associated design assumptions for drop-outs and death/lost to follow-up combined. The results for AV-1 through AV-4 (7%-11%) were higher than anticipated (6-9%) but there is a trend toward decreasing drop-outs, with results for AV-5 and later being in the range of the projected rate. 39.9% of HRT women have stopped their study pills at some point but 64% were active at their last contact.

A small proportion (1.5% per year) of the HRT participants were expected to stop study hormone pills and begin taking hormones outside of the trial. Among hysterectomized women, the observed (design) cumulative rates are 2.9% (1.5%) at AV-1, 7.0% (4.4%) at AV-3, and 11.9% (8.7%) at AV-6, notably larger than expected. In women with a uterus, the corresponding "drop-in" rates were 2.1%, 5.6%, and 8.2%, also somewhat greater than planned.

Reasons for stopping study hormones are presented in *Table 2.4*. In these data, women may report multiple reasons. Most of the specific reasons are cited infrequently, with the exception of two health issues: Advised not to participate by health care provider (>14%) and study conflicts with

other health issues (12%-14%). We note that 8.3% of women with a uterus listed vaginal bleeding as a reason for stopping. In women with a hysterectomy, 3.9% stopped to take active HRT and 4.9% indicated that they would not be taking any HRT. Among women with a uterus, 2.7% stopped to take active HRT and 5.2% will not take any HRT. Only 0.8% of women in either stratum stopped to take SERMS or other hormone medications. *Table 2.5* displays reasons for stopping by age in women without and with a uterus. A similar breakdown by race/ethnicity is provided in *Table 2.6*.

2.3 Symptoms

Women may report symptoms potentially related to HRT at routine follow-up contacts or through non-routine contacts with the CC. The primary symptoms being monitored are bleeding and breast changes. Reports of bleeding and breast changes by contact type and treatment arms are shown in *Tables 2.7* and *2.8*, respectively. Reports of bleeding in women with a uterus reached a high of nearly 30% at 6 months (SAV-1), declining to approximately 5% after AV-5. Reports of breast changes peaked at 6 weeks after randomization and have declined to less than 2% in both strata.

2.4 Safety Monitoring

Table 2.9 presents results of endometrial aspirations by time since randomization. As routine post-randomization biopsies are required of only a small sample (6%) of women at AV-3, AV-6, and AV-9, the vast majority of these tests represent non-routine aspirations performed in response to bleeding problems. Among 4,820 total biopsies, 111 (2.3%) yielded an abnormal result: 65 cystic, 13 adenomatous, 24 atypia, and 9 cancer.

2.5 Laboratory Studies

Tables 2.10 and 2.11 present the results of blood specimen analyses from a small (8.6%) cohort of HRT women selected randomly at baseline for these prospective analyses. These results are essentially the same as our last report as only a few specimens remained to be analyzed. The subsample analyzed incorporated over-sampling of minorities. The results in *Table 2.10* are weighted to reflect the overall WHI-CT distribution of race/ethnicity. In *Table 2.11*, similar results are provided for each racial/ethnic group, though some groups have rather small sample sizes.

2.6 Intermediate Outcomes

Bone mineral density (BMD) measures are collected in three clinical centers (Pittsburgh, Birmingham, and Tucson) at baseline and at follow-up years 1, 3, 6, and 9. These data, shown in *Table 2.12* suggest small but significant increases in BMD between baseline and AV-1, with larger differences observed over greater follow-up time (AV-3 and AV-6) for whole body and spine. For hip, the largest increase occurs at AV-3. The pattern of treatment effects is similar in both hysterectomy strata. *Table 2.13* presents BMD data for Black/African American, Hispanic/Latino, and White women participating in the HRT component at these three centers.

2.7 Vital Status

Table 2.14 presents data on the vital status and the participation status of participants in the HRT trial. A detailed description of CCC and clinic activities to actively locate participants who do not complete their periodic visits is given in *Section 5 – Outcomes*. For operational purposes, we define CT participants to have an "unknown" participation status if there is no outcomes information from

the participant for 18 months and no other contacts for 6 months. Currently, 3.9% of the HRT participants are lost-to-follow-up or have stopped follow-up (an increase of 0.6% compared to six months ago), and 2.3% of the participants are known to be deceased. Virtually all of the remaining participants have completed a *Form 33 – Medical History Update* in the last 18 months. The design assumed that 3% per year would be lost-to-follow-up or dead. Currently, the average follow-up for HRT participants is about 4.6 years, suggesting that approximately 13.1% could be expected to be dead or lost-to-follow-up. Our overall rates compare favorably to design assumptions. Follow-up in women with a uterus is slightly better than in women who have had a hysterectomy.

2.8 Outcomes

Table 2.15 contains counts of the number of locally verified major WHI outcomes for HRT participants by age and race/ethnicity. The estimates of annualized incidence rates for many event types in several racial/ethnic subgroups should be viewed with caution as the small number of events observed to-date results in unstable estimates. Approximately 5% of the self-reported outcomes have not yet been verified, so the numbers in this table can be seen as a lower bound of the actual number of outcomes that have occurred.

Compared to the design assumptions, we have observed about 65% of the expected number of CHD events, 75% of the expected number of breast cancers, 80% of the expected number of colorectal cancers, and about 35% of the expected number of hip fractures.

We have classified the strokes among HRT participants in one of six classes of the Glasgow scale, based on the condition of the participant at discharge:

1. Good recovery – participant can lead a full and independent life with or without minimal neurological deficit.

2. Moderately disabled – participant has neurological or intellectual impairment but is independent.

3. Severely disabled – participant conscious but totally dependent on others to get through daily activities.

4. Vegetative survival – participant has no obvious cortical functioning.

5. Dead. (All participants who died within one month of their stroke were classified in this category, irrespective of their actual cause of death.)

6. Unable to categorize based on available documentation.

The subclass *Non-disabling stroke* contains strokes with Glasgow scale class 1 and 2; *Fatal/ disabling stroke* contains strokes with Glasgow scale class 3 through 5; *Unknown status from stroke* contains strokes with Glasgow scale 6 and strokes for which the Glasgow classification was not yet complete.

Table 2.16 compares the rates of the same locally verified outcomes according to baseline hysterectomy strata. For most cardiovascular outcomes the event rates are slightly larger for the women without a uterus, while for most cancers the rates are slightly larger for women with a

uterus. The differences in cardiovascular disease rates are consistent with the risk profile differences we have previously observed.

Table 2.17 compares the stroke diagnosis for HRT participants with and without a uterus. The distribution of the subtype of stroke appears to be similar for the women with and without a uterus. *Table 2.18* compares the Glasgow scale for strokes among HRT participants. From this table it appears that the largest number of strokes fall in Glasgow classes 1 and 2, the less disabling strokes, but a substantial number of participants die within one month of a stroke.

Table 2.19 contains counts of the number of self-reports for some outcomes that are not locally verified in WHI. As most of the self-reported outcomes are somewhat over-reported (see *Section 6.3 – Outcomes Data Quality*), the numbers in this table should be taken as an upper bound on the number of events that have occurred in HRT participants.

2.9 Power Considerations

The power under the design assumptions for adherence and overall incidence rates and values derived from the observed data through February 29, 2000 are shown in *Table 2.20*. Because no significant changes have been observed in the key design parameters since that time, these calculations have not been further updated. These calculations use a drop-out rate of 7% in years 1 and 2, and 4% per year through the remaining follow-up (independent of the 3% lost-to-follow-up rates). The drop-in rates are 2.5% per year throughout follow-up. CHD incidence rates were adjusted to reflect the lower rates observed in the early follow-up period. In addition to the 33% reduction for healthy volunteer effect that the design assumed throughout follow-up, incidence rates in years 1, 2, and 3 were further reduced by 67%, 50%, and 37%, respectively. These changes produced a power for the ERT vs. Placebo comparison on CHD rates of 63% compared to the design value of 81%. For the PERT comparison the power drops from 88% to 76%.

2.10 WHI Memory Study – WHIMS

The WHI Memory Study is an ancillary study in the HRT component, funded by Wyeth Ayerst through a grant to Dr. Sally Shumaker, Wake Forest University. The aim of this study is to determine whether hormone replacement therapy reduces the incidence of dementia in women over 65 years of age. 7,526 women were enrolled in the 39 participating centers, representing approximately 61% of the age eligible cohort and 28% of the entire HRT study cohort. Baseline characteristics of WHIMS participants are shown in *Table 2.21* by hysterectomy strata.

HRT women over 65 years of age are to be administered the Modified Mini-Mental Status instrument (*Form 39—Cognitive Function*) at baseline and years 1, 3, 6, and 9 of follow-up as part of WHI. The WHIMS protocol asks that the same instrument be administered to WHIMS participants in the intervening years. *Table 2.22* presents the 25th and 50th percentile of the distribution of F39 scores in the entire HRT cohort and the subset participating in WHIMS by treatment arm and visit type. Percentile scores are reported as the scores for this population are highly skewed. These data suggest that participants who enrolled in WHIMS have slightly better F39 cognitive function scores than those who declined to participate.

Women who score below an education-adjusted threshold are referred for an intensive cognitive and neurological evaluation (Phase II/III). The results of these tests are used to classify participants into four categories: probable dementia (PD); minor cognitive impairment (MCI); no dementia (ND); or

refused the Phase II/III exam (REF). *Table 2.23* describes this cascade of events by hysterectomy strata.

2.11 Issues

The primary issues of concern in the HRT trial have been around adherence and the notification to participants of the early adverse effects. The notification has taken place to all HRT participants in the form of a letter and brochure ("HRT Update"). For the most part, the participants have accepted the information without alarm. There have been anecdotal reports of women dropping out after receiving this information, the data available to us at this point provide no evidence of important changes to participation or adherence to medications.

Methods to maintain and improve adherence continue to be discussed by study investigators. The current adherence rates are well above that expected from community-based estimates of hormone use but the study design projected even better rates. Continued efforts are needed to monitor and understand women's acceptance or refusal of long-term hormones. Creative approaches to motivate study participants with low impact to the clinical centers would be most welcome.

Table 2.1
Hormone Replacement Therapy Component Age – and Race/Ethnicity – Specific Recruitment

Data as of: August 31, 2001

HRT Participants	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age				
Overall	**27,347**			
50-54	3425	125%	13%	10
55-59	5407	99%	20%	20
60-69	12365	100%	45%	45
70-79	6150	90%	22%	25
Without Uterus	**10,739**			
50-54	1396	113%	13%	10
55-59	1916	78%	18%	20
60-69	4852	88%	45%	45
70-79	2575	84%	24%	25
With uterus	**16,608**			
50-54	2029	135%	12%	10
55-59	3491	116%	21%	20
60-69	7513	111%	45%	45
70-79	3575	95%	22%	25
Race/Ethnicity				
Overall	**27,347**			
American Indian	130		<1%	
Asian	527		2%	
Black	2738		10%	
Hispanic	1537		6%	
White	22030		81%	
Other/unspecified	385		1%	
Without Uterus	**10,739**			
American Indian	75		1%	
Asian	164		2%	
Black	1616		15%	
Hispanic	651		6%	
White	8084		75%	
Other/unspecified	149		1%	
With uterus	**16,608**			
American Indian	55		<1%	
Asian	363		2%	
Black	1122		7%	
Hispanic	886		5%	
White	13946		84%	
Other/unspecified	236		1%	

Table 2.2
HRT Adherence Summary

Data as of: August 31, 2001

Contact	Due N	Conducted N	Conducted %	Conducted in Window N	Conducted in Window %	Stopped HRT during interval N	Stopped HRT during interval %	Missed Pill Collection N	Missed Pill Collection %	Total with Collections N	Total with Collections %	Medication Rate[1] <50% N	Medication Rate[1] <50% %	Medication Rate[1] 50%-80% N	Medication Rate[1] 50%-80% %	Medication Rate[1] 80% + N	Medication Rate[1] 80% + %	Adherence Summary[2] %
Semi-Annual Visit-1	27347	26709	98	22784	83	1360	5	1423	5	25553	95	1040	4	1905	8	22608	89	84
Annual Visit-1	27347	26502	97	21882	80	1285	5	1401	6	23803	94	1035	4	2069	9	20699	87	77
Annual Visit-2	27347	25897	95	20506	75	2474	9	2414	10	21176	90	763	4	2028	10	18385	87	69
Without Uterus	10739	10064	94	7943	74	1064	10	1052	11	8272	89	275	3	887	11	7110	86	67
With Uterus	16608	15833	95	12563	76	1410	9	1362	10	12904	91	488	4	1141	9	11275	87	70
Annual Visit –3	27268	25636	94	19070	70	1971	7	1739	8	19391	92	750	4	1884	10	16757	86	63
Without Uterus	10705	9973	93	7429	69	835	8	747	9	7517	91	271	4	801	11	6445	86	61
With Uterus	16563	15663	95	11641	70	1136	7	992	8	11874	92	479	4	1083	9	10312	87	64
Annual Visit –4	20923	19299	92	13845	66	1270	6	1205	8	13671	92	531	4	1262	9	11878	87	59
Without Uterus	8243	7490	91	5376	65	546	7	520	9	5305	91	204	4	514	10	4587	87	57
With Uterus	12680	11809	93	8469	67	724	6	685	8	8366	92	327	4	748	9	7291	87	60
Annual Visit –5	11300	10283	91	7325	65	586	6	625	8	6798	92	241	4	645	10	5912	87	55
Without Uterus	4516	4052	90	2896	64	242	6	247	8	2698	92	101	4	284	11	2313	86	52
With Uterus	6784	6231	92	4429	65	344	5	378	8	4100	92	140	3	361	9	3599	88	57
Annual Visit –6	4807	4368	91	2946	61	199	5	211	7	2649	93	99	4	232	9	2318	88	53
Without Uterus	1965	1773	90	1191	61	82	4	89	8	1095	93	39	4	96	9	960	88	50
With Uterus	2842	2595	91	1755	62	117	5	122	7	1554	93	60	4	136	9	1358	87	56
Annual Visit –7	1304	1144	88	750	58	40	4	61	9	626	91	25	4	68	11	533	85	49
Without Uterus	545	469	86	301	55	17	3	27	8	296	92	9	3	27	9	260	88	49
With Uterus	759	675	89	449	59	23	4	34	9	330	91	16	5	41	12	273	83	48

[1] Medication rate calculated as number of pills taken divided by number of days since bottle(s) were dispensed.
[2] Adherence summary calculated as number of women consuming ≥ 80% of pills / # due for visit.
Note: Deceased women are excluded from all medication adherence calculations, but are included in the number "Due."

Figure 2.1
HRT Adherence Summary
% Participants Due for a Visit Who Took at Least 80% of Study Pills

Data as of August 31, 2001

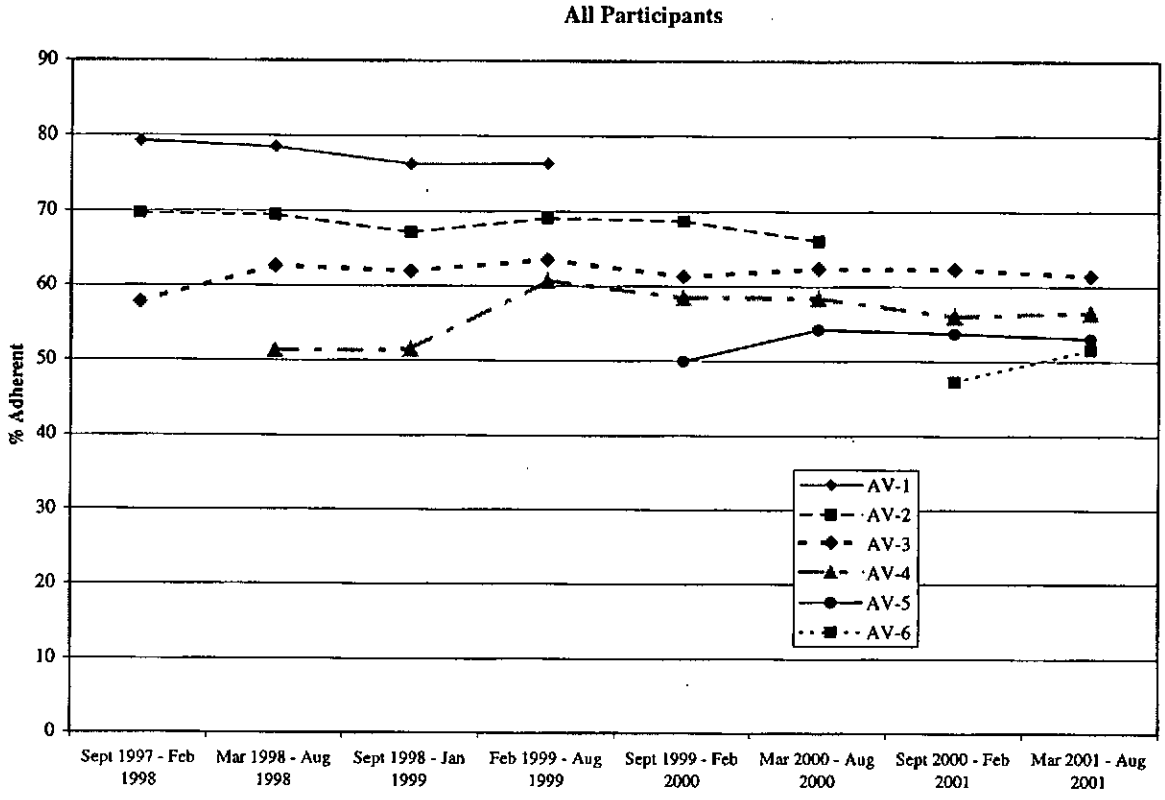
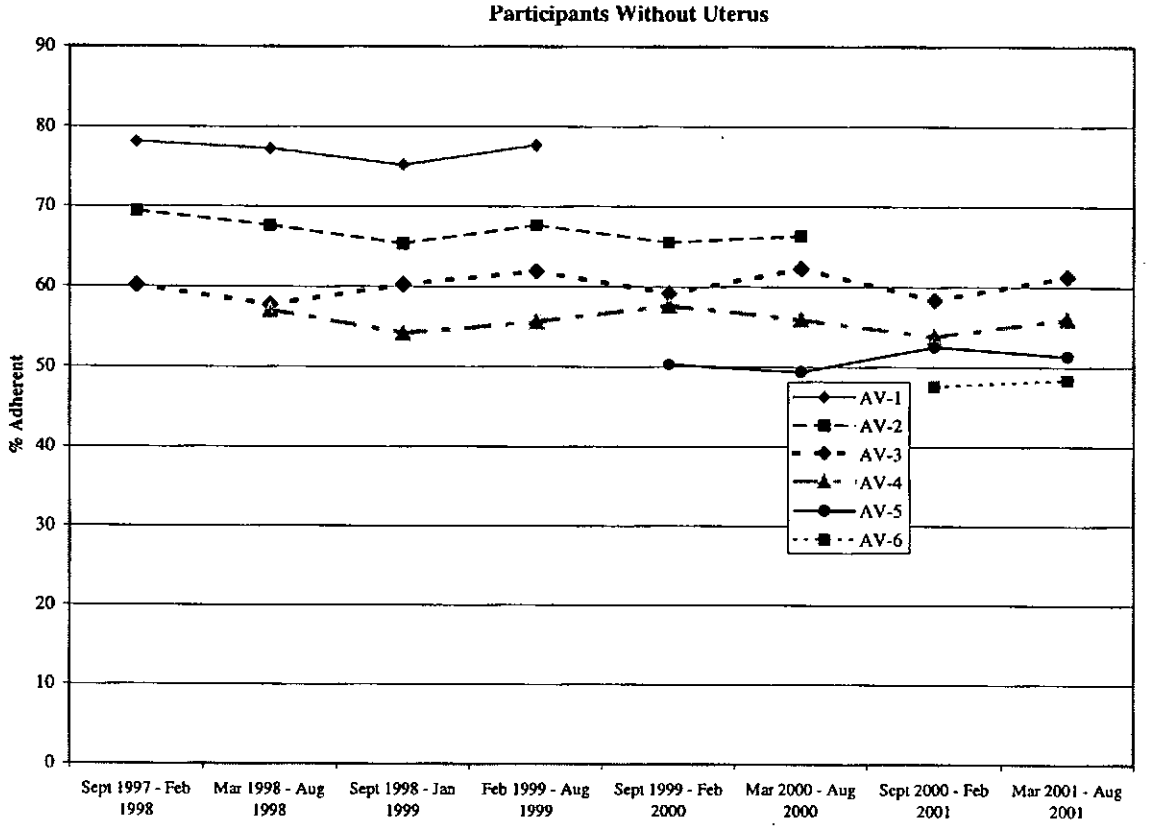


Figure 2.1 (continued)
HRT Adherence Summary
% Participants Due for a Visit Who Took at Least 80% of Study Pills

Data as of August 31, 2001



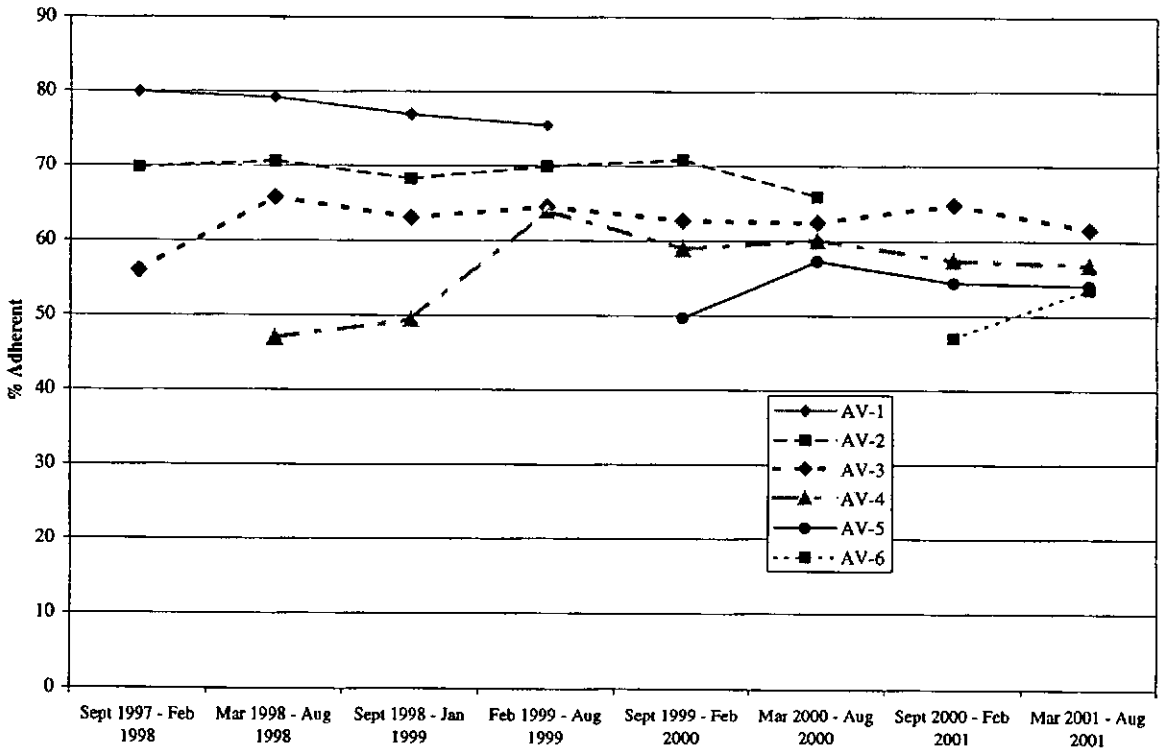


Table 2.3
HRT Drop-Out and Drop-In Rates by Follow-Up Time

Data as of: August 31, 2001

	Design		Without Uterus				With Uterus			
	Int	Cum	Stopped[1]	Dead/ Lost[2]	Int[3]	Cum[4]	Stopped[1]	Dead/ Lost[2]	Int[3]	Cum[4]
Drop-Outs[5]										
AV-1	8.8	8.8	9.7	1.0	10.7	10.7	9.6	1.0	10.5	10.5
AV-2	5.9	14.2	10.0	1.3	11.3	20.8	8.7	1.0	9.7	19.2
AV-3	5.9	19.2	7.9	1.5	9.4	28.2	7.1	1.0	8.1	25.7
AV-4	5.9	24.0	6.8	1.3	8.1	34.0	6.0	1.1	7.1	31.0
AV-5	5.9	28.5	5.5	1.1	6.6	38.4	5.4	1.2	6.6	35.6
AV-6	5.9	32.7	4.3	1.4	5.7	41.9	4.8	0.9	5.7	39.2
AV-7	5.9	36.7	3.2	1.7	4.9	44.7	4.0	1.9	5.9	42.8
Drop-Ins[6]										
AV-1	1.5	1.5			2.9	2.9			2.1	2.1
AV-3	2.9	4.4			4.2	7.0			3.6	5.6
AV-6	4.4	8.7			4.3	11.0			2.8	8.2

[1] Estimated rate of stopping hormones in the interval.
[2] Death or lost to follow-up rate in the interval.
[3] Combined rate of stopping and death or lost to follow-up in the interval.
[4] Estimated cumulative rate of stopping and death or lost to follow-up.
[5] Drop-out rates derived from Form 7 by date. Cumulative rates calculated as life-table estimates.
[6] Cumulative Drop-in rates derived from medication inventory collected at AV-1, AV-3, AV-6, AV-9. Interval estimates back-calculated from cumulative rates.

Table 2.4
Reasons for Stopping HRT[1]

Data as of August 31, 2001

Reasons[2]	Without Uterus (N = 4102)		With Uterus (N = 5776)	
Personal/family				
Demands of work	77	1.9%	106	1.8%
Family illness, emergency or other family demands[3]	173	4.2%	210	3.6%
Financial problems	9	0.2%	7	0.1%
Lack of cooperation/support from family/friends[4]	38	0.9%	57	1.0%
Living in nursing home	7	0.2%	15	0.3%
Issues of interest in study[5]	82	2.0%	108	1.9%
Travel				
Too far to CC	147	3.6%	154	2.7%
Moved out of area or refuses to be followed to another CC	28	0.7%	30	0.5%
Other travel issues[6]	88	2.1%	62	1.1%
Visits & Procedures				
Doesn't like visits, calls	50	1.2%	37	0.6%
Mammogram Issues[7]	15	0.4%	18	0.3%
Doesn't like gynecologic procedures	10	0.2%	42	0.7%
Doesn't like required forms or safety procedures[8]	69	1.7%	88	1.5%
Problems with other procedures[9]	9	0.2%	20	0.3%
Worried about health effects of medical tests/procedures	18	0.4%	22	0.4%
Wants test results[10]	1	<0.1%	2	<0.1%
Problems with CC[11]	25	0.6%	47	0.8%

(continues)

[1] Does not include reasons reported by women who stopped and later restarted HRT.
[2] Multiple reasons may be reported for a woman.
[3] Combines "Family illness, emergency or other family demands", "Death in the family or of a close friend", and "Caregiver responsibilities demanding time, effort, lifestyle changes".
[4] Combines "Lack of cooperation/support from family and/or friends" and "Family/friends request that she withdraw".
[5] Combines "Conflicting priorities other than work or family", "Feels discouraged regarding participation overall", "Loss of interest, boredom", "Feels it is not an important study", and "In another study in conflict with WHI intervention".
[6] Combines "Transportation problems (other than distance)", "Traffic", "Parking at CC", and "CC neighborhood/safety".
[7] Combines "Doesn't like mammograms (DM, HRT)" and "Cost of mammograms (DM, HRT)".
[8] Combines "Doesn't like filling out forms (other than those required for safety)", and "Doesn't like required safety forms and/or procedures (HRT, CaD)".
[9] Combines "Doesn't like having blood drawn", "Doesn't like ECG (DM, HRT)", and "Doesn't like other procedures (other than those required for safety)".
[10] Combines "Wants results of blood analyses", and "Wants results of bone mineral density measurement (BD sites only)".
[11] Combines "Problem with the CC", "Problem with CC staff person (other than DM Group Nutritionist)", and "Staff change/turnover".

Table 2.4 (Continued)
Reasons for Stopping HRT[1]

Data as of August 31, 2001

Reasons[2]	Without Uterus (N = 4102)		With Uterus (N = 5776)	
Symptoms				
Vaginal Bleeding	4	0.1%	481	8.3%
Breast Symptoms[3]	166	4.0%	259	4.5%
Vaginal Changes	14	0.3%	12	0.2%
Hot flashes/night sweats	25	0.6%	7	0.1%
Other[4]	1019	24.8%	1465	25.4%
Health Conditions				
Breast Cancer	51	1.2%	109	1.9%
Complex or atypical hyperplasia	0	0.0%	5	0.1%
Endometrial cancer	2	<0.1%	15	0.3%
Venous thromboembolism[5]	28	0.7%	63	1.1%
High triglycerides (> 1000 mg/dL)	1	<0.1%	5	0.1%
Malignant melanoma	5	0.1%	17	0.3%
Gallbladder disease	3	0.1%	3	0.1%
Heart Attack	35	0.9%	25	0.4%
Stroke	48	1.2%	70	1.2%
Meningioma	3	0.1%	1	<0.1%
Depression	9	0.2%	9	0.2%
Cholesterol (high or concern about levels)	8	0.2%	1	<0.1%
Osteoporosis	29	0.7%	35	0.6%
Cognitive/memory changes	9	0.2%	24	0.4%
Other[6]	374	9.1%	568	9.8%

(continues)

[1] Does not include reasons reported by women who stopped and later restarted HRT.
[2] Multiple reasons may be reported for a woman.
[3] Combines "Breast tenderness (HRT)" and "Other breast changes (HRT)".
[4] Combines "Experiencing health problems or symptoms not due to intervention", "Reports other health problems or symptoms from the WHI intervention", "Reports health problems or symptoms from the WHI intervention", "Hair/skin changes", "Bloating/Gas", "Constipation", "Other gastrointestinal problems", "Headaches", "Weight loss/gain", "Low energy/too tired", "Possible allergic reaction", and "Other symptoms not listed above".
[5] Combines "Deep vein thrombosis", and "Pulmonary embolism".
[6] Combines "Removed from intervention due to WHI symptom management", "Removed from intervention due to adverse health event", "Communication problem", "Hypercalcemia", "Kidney failure/dialysis", "Renal calculi", "Arthritis", "Diabetes", "Loss of vision and/or hearing", and "Other health conditions not listed above".

Table 2.4 (Continued)
Reasons for Stopping HRT[1]

Data as of August 31, 2001

Reasons[2]	Without Uterus (N = 4102)		With Uterus (N = 5776)	
Intervention				
Doesn't like randomized nature of intervention	80	2.0%	123	2.1%
Expected some benefit from intervention	38	0.9%	39	0.7%
Feels guilty, unhappy, or like a failure for not meeting study goals of intervention	3	0.1%	6	0.1%
Takes too many pills	22	0.5%	23	0.4%
Other pill issues[3]	118	2.9%	135	2.3%
CaD Issues[4]	21	0.5%	20	0.3%
DM Issues[5]	4	0.1%	10	0.2%
Taking active HRT[6]	161	3.9%	157	2.7%
Will not be on any HRT[7]	201	4.9%	300	5.2%
Taking SERMs or other hormone medications[8]	32	0.8%	47	0.8%
Other Health Issues				
Worried about cost if adverse effects occur	11	0.3%	6	0.1%
Expected more health care	12	0.3%	15	0.3%
Advised not to participate by health care provider[9]	613	14.9%	825	14.3%
Study conflicts with other health issues[10]	580	14.1%	705	12.2%
Other				
Other reasons not listed above	895	21.8%	1181	20.4%
Refuses to give a reason	68	1.7%	82	1.4%

[1] Does not include reasons reported by women who stopped and later restarted HRT.
[2] Multiple reasons may be reported for a woman
[3] Combines "Doesn't like taking pills (HRT, CaD)", "Doesn't like taste of pills (HRT, CaD)", and "Unable to swallow pills (HRT, CaD)".
[4] Combines "Wants to take her own calcium (CaD)", "Feels diet is already sufficient in calcium/Vitamin D (CaD)", "Taking more than the maximum allowable IU of Vit D (CaD)", and "Taking Calcitriol (CaD)".
[5] Combines "Doesn't like DM requirements", "Problem with DM Group Nutritionist or group members (DM)", "Doesn't like DM eating pattern", "Doesn't like attending DM intervention classes (DM)", "Doesn't like self-monitoring (DM)", "Doesn't like budgeting fat grams (DM)", "Has concerns regarding long-term risks/benefits of low fat diet (DM)", "Unhappy that not losing weight (DM)", "Not in control of meal preparation (DM)", "Too difficult to meet or maintain dietary goals (DM)", "Doesn't like eating low fat diet (DM)", "Doesn't like eating 5 vegetables/fruits per day (DM)", "Doesn't like eating 6 grains per day (DM)", "Feels fat gram goal is unrealistic (DM)", and "Eating pattern conflicts with personal health beliefs (DM)".
[6] Combines "Has made a personal decision to go on active HRT (HRT)" and "Advised to go on active HRT by health care provider (HRT)".
[7] Combines "Has made a personal decision that she does not want to be on HRT (HRT)" and "Advised to not be on active HRT by health care provider (HRT)".
[8] Combines "Has made a personal decision to go on SERM (e.g., Evista/raloxifene, tamoxifen) (HRT)", "Advised to go on SERM (e.g., Evista/raloxifene, tamoxifen) by health care provider (HRT)", and "Taking testosterone medications (HRT)".
[9] Combines "Advised not to participate by health care provider" and "Advised not to participate by health care provider for other reason".
[10] Combines "Study conflicts with health care needs" and "Study conflicts with other health issues".

Table 2.5
Reasons for Stopping HRT by Age at Screening[1]: HRT Participants

Data as of August 31, 2001

			Age at Screening							
	All (N = 10,739)		50 – 54 (N = 1,396)		55 –59 (N = 1,916)		60 –69 (N = 4,852)		70 –79 (N = 2,575)	
Without Uterus	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping HRT	4102	38.2%	547	39.2%	715	37.3%	1781	36.7%	1059	41.1%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Family illness, emergency, or other family demands[5]	173	4.2%	21	3.8%	33	4.6%	80	4.5%	39	3.7%
Vaginal bleeding	4	0.1%	1	0.2%	2	0.3%	1	0.1%	0	0.0%
Breast symptoms[6]	166	4.0%	12	2.2%	19	2.7%	67	3.8%	68	6.4%
Taking active HRT[7]	161	3.9%	20	3.7%	37	5.2%	68	3.8%	36	3.4%
Will not be on any HRT[8]	201	4.9%	16	2.9%	23	3.2%	95	5.3%	67	6.3%
Advised not to participate by health care provider[9]	613	14.9%	85	15.5%	101	14.1%	263	14.8%	164	15.5%
Study conflicts with other health issues[10]	580	14.1%	82	15.0%	95	13.3%	254	14.3%	149	14.1%
	(N = 16,608)		(N = 2,029)		(N = 3,491)		(N = 7,513)		(N = 3,575)	
With Uterus	N	%[11]	N	%[11]	N	%[11]	N	%[11]	N	%[11]
Women Stopping HRT	5776	34.8%	705	34.7%	1131	32.4%	2544	33.9%	1396	39.0%
REASONS FOR STOPPING[3]	N	%[12]	N	%[12]	N	%[12]	N	%[12]	N	%[12]
Family illness, emergency, or other family demands[5]	210	3.6%	19	2.7%	41	3.6%	97	3.8%	53	3.8%
Vaginal bleeding	481	8.3%	35	5.0%	66	5.8%	239	9.4%	141	10.1%
Breast symptoms[6]	259	4.5%	11	1.6%	35	3.1%	118	4.6%	95	6.8%
Taking active HRT[7]	157	2.7%	18	2.6%	35	3.1%	72	2.8%	32	2.3%
Will not be on any HRT[8]	300	5.2%	20	2.8%	59	5.2%	141	5.5%	80	5.7%
Advised not to participate by health care provider[9]	825	14.3%	104	14.8%	157	13.9%	382	15.0%	182	13.0%
Study conflicts with other health issues[10]	705	12.2%	88	12.5%	151	13.4%	305	12.0%	161	11.5%

[1] Does not include reasons reported by women who stopped and later restarted HRT.
[2] Percentages are of HRT participants without uterus in the same age category.
[3] Multiple reasons may be reported for a woman.
[4] Percentages are of HRT participants without uterus in the same age category who stopped HRT.
[5] Combines "Family illness, emergency or other family demands", "Death in the family or of a close friend", and "Caregiver responsibilities demanding time, effort, lifestyle changes".
[6] Combines "Breast tenderness (HRT)" and "Other breast changes (HRT)".
[7] Combines "Has made a personal decision to go on active HRT (HRT)" and "Advised to go on active HRT by health care provider (HRT)".
[8] Combines "Has made a personal decision that she does not want to be on HRT (HRT)" and "Advised to not be on active HRT by health care provider (HRT)".
[9] Combines "Advised not to participate by health care provider" and "Advised not to participate by health care provider for other reason".
[10] Combines "Study conflicts with health care needs" and "Study conflicts with other health issues".
[11] Percentages are of HRT participants with uterus in the same age category.
[12] Percentages are of HRT participants with uterus in the same age category who stopped HRT.

Table 2.6
Reasons for Stopping HRT by Race/Ethnicity[1]: HRT Participants

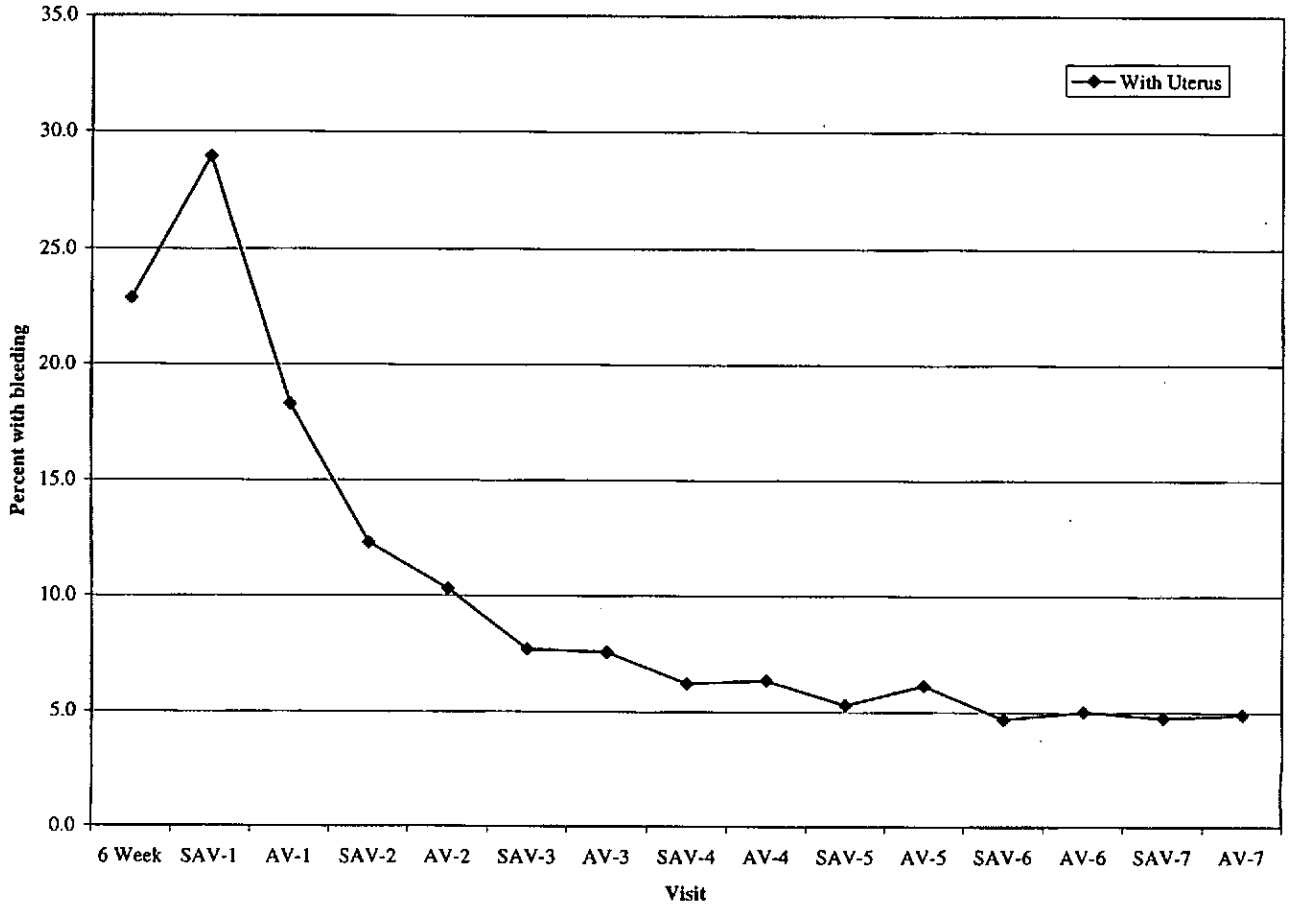
Data as of August 31, 2001

	Race/Ethnicity											
	American Indian/ Alaskan Native (N = 75)		Asian/Pacific Islander (N = 164)		Black/African American (N = 1,616)		Hispanic/Latino (N = 651)		White (N = 8,084)		Other/ Unspecified (N = 149)	
Without Uterus	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping HRT	28	37.3%	54	32.9%	639	39.5%	297	45.6%	3026	37.4%	58	38.9%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Family illness, emergency, or other family demands[5]	1	3.6%	2	3.7%	38	5.9%	19	6.4%	111	3.7%	2	3.4%
Vaginal bleeding	0	0.0%	0	0.0%	1	0.2%	1	0.3%	2	0.1%	0	0.0%
Breast symptoms[6]	1	3.6%	2	3.7%	23	3.6%	11	3.7%	127	4.2%	2	3.4%
Taking active HRT[7]	0	0.0%	0	0.0%	20	3.1%	8	2.7%	130	4.3%	3	5.2%
Will not be on any HRT[8]	1	3.6%	2	3.7%	28	4.4%	9	3.0%	157	5.2%	4	6.9%
Advised not to participate by health care provider[9]	5	17.9%	10	18.5%	65	10.2%	35	11.8%	489	16.2%	9	15.5%
Study conflicts with other health issues[10]	6	21.4%	11	20.4%	65	10.2%	27	9.1%	464	15.3%	7	12.1%
	(N = 55)		(N = 363)		(N = 1,122)		(N = 886)		(N = 13,946)		(N = 236)	
With Uterus	N	%[11]	N	%[11]	N	%[11]	N	%[11]	N	%[11]	N	%[11]
Women Stopping HRT	22	40.0%	102	28.1%	448	39.9%	344	38.8%	4774	34.2%	86	36.4%
REASONS FOR STOPPING[3]	N	%[12]	N	%[12]	N	%[12]	N	%[12]	N	%[12]	N	%[12]
Family illness, emergency, or other family demands[5]	0	0.0%	2	2.0%	26	5.8%	13	3.8%	162	3.4%	7	8.1%
Vaginal bleeding	2	9.1%	6	5.9%	48	10.7%	23	6.7%	394	8.3%	8	9.3%
Breast symptoms[6]	1	4.5%	2	2.0%	17	3.8%	14	4.1%	221	4.6%	4	4.7%
Taking active HRT[7]	3	13.6%	3	2.9%	11	2.5%	5	1.5%	134	2.8%	1	1.2%
Will not be on any HRT[8]	0	0.0%	10	9.8%	22	4.9%	18	5.2%	245	5.1%	5	5.8%
Advised not to participate by health care provider[9]	0	0.0%	21	20.6%	53	11.8%	39	11.3%	704	14.7%	8	9.3%
Study conflicts with other health issues[10]	1	4.5%	17	16.7%	38	8.5%	26	7.6%	615	12.9%	8	9.3%

[1] Does not include reasons reported by women who stopped and later restarted HRT.
[2] Percentages are of HRT participants without uterus in the same race/ethnicity category.
[3] Multiple reasons may be reported for a woman.
[4] Percentages are of HRT participants without uterus in the same race/ethnicity category who stopped HRT.
[5] Combines "Family illness, emergency or other family demands", "Death in the family or of a close friend", and "Caregiver responsibilities demanding time, effort, lifestyle changes".
[6] Combines "Breast tenderness (HRT)" and "Other breast changes (HRT)".
[7] Combines "Has made a personal decision to go on active HRT (HRT)" and "Advised to go on active HRT by health care provider (HRT)".
[8] Combines "Has made a personal decision that she does not want to be on HRT (HRT)" and "Advised to not be on active HRT by health care provider (HRT)".
[9] Combines "Advised not to participate by health care provider" and "Advised not to participate by health care provider for other reason".
[10] Combines "Study conflicts with health care needs" and "Study conflicts with other health issues".
[11] Percentages are of HRT participants with uterus in the same race/ethnicity category.
[12] Percentages are of HRT participants with uterus in the same race/ethnicity category who stopped HRT.

Table 2.7
Reports of Bleeding

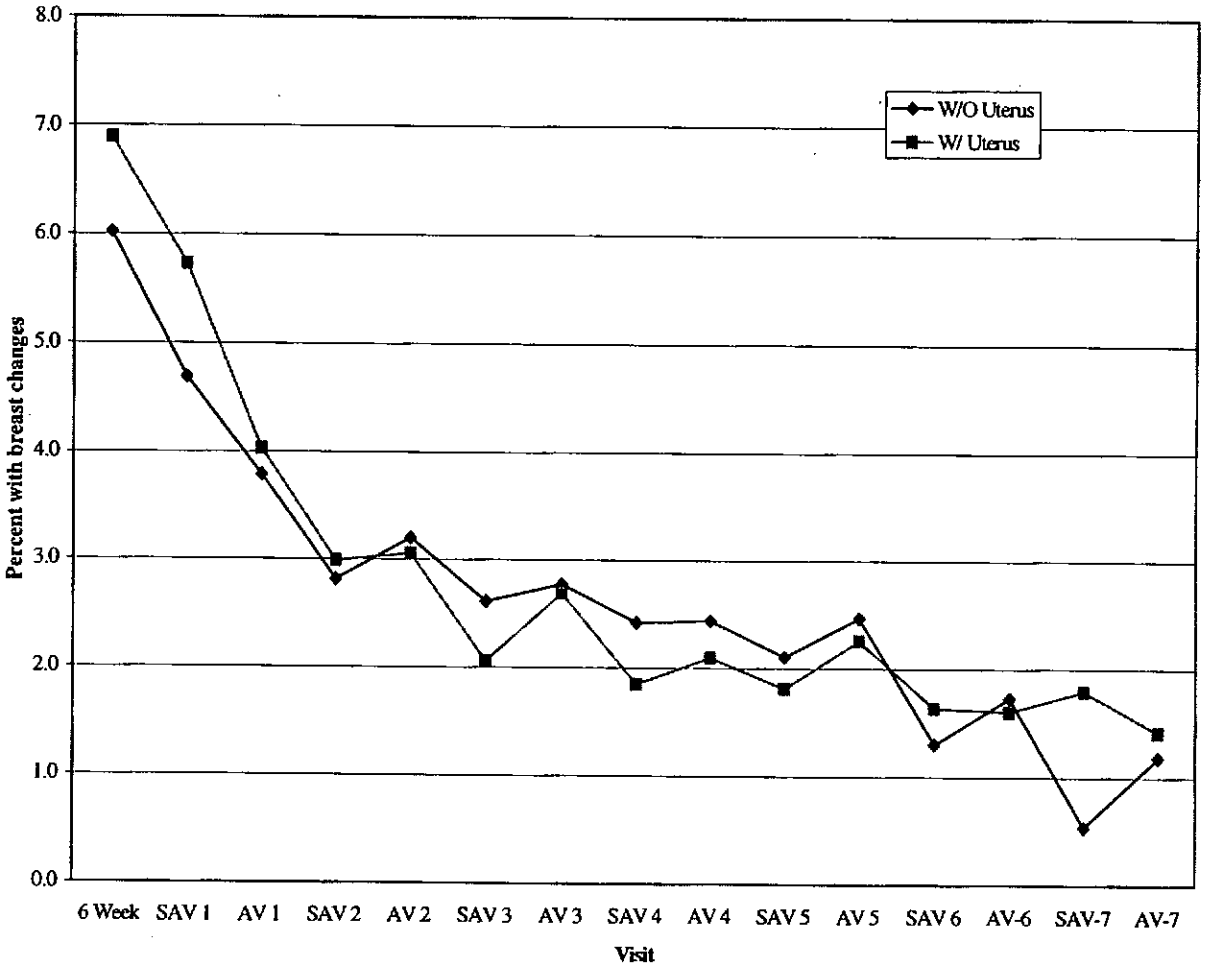
Data as of: August 31, 2001



Contact	With Uterus	
Semi-Annual Visit 3 – Number with Bleeding	1194	(7.7%)
Annual Visit 3 – Number with Bleeding	1185	(7.6%)
Semi-Annual Visit 4 – Number with Bleeding	871	(6.2%)
Annual Visit 4 – Number with Bleeding	751	(6.4%)
Semi-Annual Visit 5 – Number with Bleeding	471	(5.3%)
Annual Visit 5 – Number with Bleeding	383	(6.1%)
Semi-Annual Visit 6 – Number with Bleeding	198	(4.7%)
Annual Visit 6 – Number with Bleeding	130	(5.0%)
Semi-Annual Visit 7 – Number with Bleeding	72	(4.7%)
Annual Visit 7 – Number with Bleeding	33	(4.9%)

Table 2.8
Reports of Breast Changes

Data as of: August 31, 2001



Contact	Without Uterus		With Uterus	
Semi-Annual Visit 3 – Number with Breast Changes	220	(2.6%)	274	(2.1%)
Annual Visit 3 – Number with Breast Changes	229	(2.8%)	353	(2.7%)
Semi-Annual Visit 4 – Number with Breast Changes	172	(2.4%)	210	(1.8%)
Annual Visit 4 – Number with Breast Changes	143	(2.4%)	199	(2.1%)
Semi-Annual Visit 5 – Number with Breast Changes	92	(2.1%)	126	(1.8%)
Annual Visit 5 – Number with Breast Changes	76	(2.5%)	110	(2.3%)
Semi-Annual Visit 6 – Number with Breast Changes	26	(1.3%)	52	(1.6%)
Annual Visit 6 – Number with Breast Changes	22	(1.7%)	31	(1.6%)
Semi-Annual Visit 7 – Number with Breast Changes	4	(0.5%)	20	(1.8%)
Annual Visit 7 – Number with Breast Changes	4	(1.2%)	7	(1.4%)

Table 2.9
Endometrial Aspiration Results

Data as of: August 31, 2001

Months since randomized	N of aspirations[2,3]	Number with Abnormal Results[1]				
		Cystic	Adenomatous	Atypia	Cancer	Total[4]
0-6	104	5	1	1	-	2
6-12	723	11	2	4	-	6
12-18	708	13	3	3	3	9
18-24	531	15	4	3	-	7
24-36	404	3	-	1	-	1
36-42	702	2	-	4	3	7
42-48	647	3	2	3	1	6
48-54	290	4	-	1	-	1
54-60	241	2	-	1	-	1
60-66	165	3	-	-	-	-
66-72	108	1	-	-	1	1
72-78	89	-	-	-	1	1
78-84	89	3	1	2	-	3
84-90	10	-	-	1	-	1
90-96	9	-	-	-	-	-
Total	4820	65	13	24	9	46

[1] Abnormal results are based on local readings with the following groupings defined as follows:
Cystic is cystic hyperplasia without atypia
Adenomatous is adenomatous hyperplasia without atypia
Atypia is atypia or cystic or adenomatous hyperplasia with atypia

[2] All endometrial aspirations after first adenomatous or worse result removed. If participants had more than one endometrial aspiration within a 30-day period, the latest was used. Please note that routine aspirations for the Endometrial Aspiration subsample are included in this table.

[3] ERT-TO-PERT removed.

[4] Row totals combine adenomatous, atypias and cancer categories

Table 2.10
Blood Specimen Analysis: HRT Participants

Data as of: August 31, 2001

	Without Uterus			With Uterus		
	N	Mean[1]	S.D.[1]	N	Mean[1]	S.D.[1]
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	993	0.07	0.07	1318	0.09	0.08
AV-1	990	0.07	0.06	1318	0.08	0.08
AV-1 – Baseline	988	-0.01	0.06	1317	-0.01	0.06
Beta-Carotene (µg/ml)						
Baseline	992	0.28	0.26	1318	0.35	0.34
AV-1	989	0.26	0.25	1319	0.31	0.30
AV-1 – Baseline	987	-0.03	0.22	1318	-0.04	0.21
Alpha-tocopherol (µg/ml)						
Baseline	993	16.16	7.12	1318	16.36	7.78
AV-1	990	17.78	8.97	1319	16.84	7.42
AV-1 – Baseline	988	1.62	6.29	1318	0.48	5.74
Gamma-tocopherol (µg/ml)						
Baseline	993	2.50	1.69	1318	2.21	1.39
AV-1	990	2.20	1.85	1319	1.84	1.24
AV-1 – Baseline	988	-0.30	1.13	1318	-0.37	0.93
Beta-Cryptoxanthine (µg/ml)						
Baseline	993	0.08	0.07	1318	0.10	0.10
AV-1	990	0.08	0.07	1318	0.09	0.09
AV-1 - Baseline	988	0.00	0.06	1317	-0.01	0.07
Lycopene (µg/ml)						
Baseline	993	0.40	0.20	1318	0.41	0.20
AV-1	990	0.39	0.20	1319	0.40	0.19
AV-1 - Baseline	988	-0.01	0.17	1318	-0.01	0.17
Lutein and Zeaxanthin (µg/ml)						
Baseline	993	0.20	0.10	1318	0.21	0.10
AV-1	990	0.20	0.10	1319	0.21	0.10
AV-1 - Baseline	988	0.00	0.07	1318	0.00	0.07
Retinol (µg/ml)						
Baseline	993	0.60	0.15	1318	0.60	0.15
AV-1	990	0.63	0.16	1319	0.61	0.15
AV-1 - Baseline	988	0.03	0.11	1318	0.01	0.10

(continues)

[1] Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.

Table 2.10 (Continued)
Blood Specimen Analysis: HRT Participants

Data as of: August 31, 2001

	Without Uterus			With Uterus		
	N	Mean[1]	S.D.[1]	N	Mean[1]	S.D.[1]
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	963	129.39	29.19	1271	123.89	28.60
AV-1	943	139.39	35.44	1273	129.93	31.24
AV-1 – Baseline	917	10.42	25.53	1234	5.83	22.62
Factor VII C (%)[2]						
Baseline	944	129.77	27.34	1252	125.01	27.18
AV-1	931	136.12	31.91	1263	125.03	28.01
AV-1 – Baseline	889	6.12	23.96	1207	-0.53	21.86
Fibrinogen (mg/dl)						
Baseline	961	312.00	63.29	1269	307.06	59.59
AV-1	941	301.61	61.86	1270	298.55	59.02
AV-1 – Baseline	913	-11.40	52.64	1229	-8.22	52.92
Hormones / Other						
Glucose (mg/dl)						
Baseline	990	105.48	34.98	1315	100.79	27.12
AV-1	988	102.94	31.95	1316	98.96	24.79
AV-1 – Baseline	983	-2.75	21.42	1312	-1.84	17.29
Insulin (µIU/ml)						
Baseline	972	12.70	8.27	1280	11.48	6.95
AV-1	975	12.07	8.08	1276	11.38	7.22
AV-1 – Baseline	954	-0.72	5.99	1252	-0.08	5.59

(continues)

[1] Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.
[2] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.10 (Continued)
Blood Specimen Analysis: HRT Participants

Data as of: August 31, 2001

	Without Uterus			With Uterus		
	N	Mean[1]	S.D.[1]	N	Mean[1]	S.D.[1]
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	992	162.36	102.16	1318	145.85	74.13
AV-1	988	175.75	133.79	1318	148.67	74.10
AV-1 – Baseline	985	13.63	73.83	1317	2.74	55.76
Total Cholesterol (mg/dl)						
Baseline	992	230.03	41.03	1318	225.04	37.01
AV-1	988	223.94	40.49	1318	216.13	35.29
AV-1 – Baseline	985	-5.96	30.00	1317	-8.93	28.25
LDL-C (mg/dl)						
Baseline	971	142.27	37.00	1297	138.72	33.08
AV-1	967	128.90	35.75	1296	127.25	32.55
AV-1 – Baseline	954	-13.24	27.42	1283	-11.39	25.71
HDL-C (mg/dl)						
Baseline	988	55.99	14.60	1313	57.07	14.47
AV-1	986	60.20	16.85	1318	59.35	14.96
AV-1 – Baseline	981	4.17	9.37	1312	2.27	8.15
HDL-2 (mg/dl)						
Baseline	964	17.39	7.63	1276	17.96	7.68
AV-1	963	19.52	8.81	1286	19.24	8.17
AV-1 – Baseline	940	2.07	5.06	1250	1.20	4.69
HDL-3 (mg/dl)						
Baseline	965	38.71	8.41	1276	39.05	8.13
AV-1	965	40.98	9.52	1287	40.15	8.21
AV-1 – Baseline	942	2.14	5.77	1251	1.04	5.24
Lp(a) (mg/dl)						
Baseline	975	26.47	26.57	1299	27.07	28.01
AV-1	973	25.38	27.19	1305	25.09	27.54
AV-1 – Baseline	960	-1.04	10.81	1288	-1.91	10.76

[1] Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.

Table 2.11
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: August 31, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	27	0.06	0.05	24	0.05	0.04
AV-1	27	0.07	0.08	24	0.05	0.03
AV-1 - Baseline	27	0.01	0.06	24	-0.01	0.03
Beta-Carotene (µg/ml)						
Baseline	27	0.35	0.40	24	0.25	0.21
AV-1	27	0.34	0.39	24	0.28	0.31
AV-1 – Baseline	27	-0.02	0.24	24	0.03	0.17
Alpha-tocopherol (µg/ml)						
Baseline	27	17.86	8.05	24	12.97	5.39
AV-1	27	19.18	10.00	24	15.04	8.29
AV-1 – Baseline	27	1.33	6.21	24	2.08	8.17
Gamma-tocopherol (µg/ml)						
Baseline	27	2.60	1.68	24	3.12	1.88
AV-1	27	2.64	2.73	24	2.36	1.01
AV-1 – Baseline	27	0.04	1.81	24	-0.76	1.95
Beta-Cryptoxanthine (µg/ml)						
Baseline	27	0.09	0.12	24	0.06	0.03
AV-1	27	0.08	0.06	24	0.07	0.05
AV-1 - Baseline	27	-0.01	0.10	24	0.01	0.04
Lycopene (µg/ml)						
Baseline	27	0.36	0.19	24	0.37	0.14
AV-1	27	0.40	0.21	24	0.42	0.19
AV-1 - Baseline	27	0.03	0.21	24	0.05	0.16
Lutein and Zeaxanthin (µg/ml)						
Baseline	27	0.22	0.10	24	0.18	0.09
AV-1	27	0.25	0.15	24	0.18	0.09
AV-1 - Baseline	27	0.03	0.09	24	0.00	0.05
Retinol (µg/ml)						
Baseline	27	0.61	0.19	24	0.51	0.12
AV-1	27	0.65	0.19	24	0.54	0.15
AV-1 – Baseline	27	0.05	0.07	24	0.03	0.09

(continues)

Table 2.11 (Continued)
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: August 31, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	25	139.24	35.44	21	123.38	32.72
AV-1	26	154.77	44.02	24	127.04	36.47
AV-1 – Baseline	24	13.08	28.42	21	1.95	20.69
Factor VII C (%)[1]						
Baseline	25	135.56	27.59	21	121.14	33.52
AV-1	25	141.24	30.15	24	125.88	32.80
AV-1 – Baseline	23	6.70	16.45	21	3.90	23.09
Fibrinogen (mg/dl)						
Baseline	25	331.76	57.88	21	321.24	75.11
AV-1	26	315.69	83.44	24	308.04	78.05
AV-1 – Baseline	24	-9.04	75.45	21	-13.33	52.01
Hormones / Other						
Glucose (mg/dl)						
Baseline	27	115.89	45.22	24	113.63	44.22
AV-1	27	112.30	42.55	24	114.29	61.49
AV-1 – Baseline	27	-3.59	41.95	24	0.67	28.55
Insulin (μIU/ml)						
Baseline	27	14.08	8.46	24	12.57	8.05
AV-1	27	13.22	7.68	23	12.64	7.49
AV-1 – Baseline	27	-0.86	3.72	23	-0.26	2.88

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.11 (Continued)
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: August 31, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	26	177.81	106.80	24	153.63	87.14
AV-1	27	214.63	159.36	24	164.50	100.84
AV-1 – Baseline	26	35.85	98.82	24	10.88	56.74
Total Cholesterol (mg/dl)						
Baseline	26	237.15	41.24	24	211.96	41.54
AV-1	27	230.78	47.19	24	209.13	42.39
AV-1 – Baseline	26	-4.23	27.84	24	-2.83	19.24
LDL-C (mg/dl)						
Baseline	24	144.21	28.37	24	128.38	39.60
AV-1	23	125.13	38.01	23	123.30	40.06
AV-1 – Baseline	22	-15.77	25.61	23	-7.04	20.73
HDL-C (mg/dl)						
Baseline	26	55.00	13.69	24	52.79	13.39
AV-1	27	59.44	15.82	24	55.46	13.11
AV-1 – Baseline	26	5.04	7.68	24	2.67	7.85
HDL-2 (mg/dl)						
Baseline	26	17.08	6.12	24	16.08	5.79
AV-1	26	19.42	7.17	24	16.58	5.85
AV-1 – Baseline	25	2.68	3.67	24	0.50	4.31
HDL-3 (mg/dl)						
Baseline	27	37.81	7.99	24	36.71	8.36
AV-1	26	40.69	9.38	24	38.88	8.91
AV-1 – Baseline	26	2.69	4.87	24	2.17	4.50
Lp(a) (mg/dl)						
Baseline	26	32.58	39.67	24	15.08	15.19
AV-1	26	32.08	43.78	24	13.08	14.50
AV-1 – Baseline	26	-0.50	14.62	24	-2.00	5.50

Table 2.11 (Continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: August 31, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	44	0.13	0.11	113	0.12	0.07
AV-1	44	0.09	0.07	113	0.11	0.07
AV-1 - Baseline	44	-0.04	0.09	113	-0.01	0.07
Beta-Carotene (µg/ml)						
Baseline	44	0.53	0.45	113	0.54	0.38
AV-1	44	0.39	0.33	113	0.44	0.27
AV-1 – Baseline	44	-0.14	0.30	113	-0.10	0.30
Alpha-tocopherol (µg/ml)						
Baseline	44	20.51	8.05	113	18.84	9.18
AV-1	44	21.40	8.75	113	19.53	10.20
AV-1 – Baseline	44	0.90	5.85	113	0.69	6.09
Gamma-tocopherol (µg/ml)						
Baseline	44	1.56	1.10	113	1.52	1.06
AV-1	44	1.33	1.16	113	1.26	1.00
AV-1 – Baseline	44	-0.23	0.66	113	-0.26	0.76
Beta-Cryptoxanthine (µg/ml)						
Baseline	44	0.16	0.13	113	0.25	0.38
AV-1	44	0.17	0.20	113	0.23	0.34
AV-1 - Baseline	44	0.02	0.13	113	-0.02	0.25
Lycopene (µg/ml)						
Baseline	44	0.42	0.22	113	0.40	0.21
AV-1	44	0.35	0.19	113	0.36	0.19
AV-1 - Baseline	44	-0.07	0.19	113	-0.04	0.19
Lutein and Zeaxanthin (µg/ml)						
Baseline	44	0.30	0.14	113	0.28	0.11
AV-1	44	0.28	0.13	113	0.28	0.12
AV-1 - Baseline	44	-0.02	0.08	113	-0.01	0.09
Retinol (µg/ml)						
Baseline	44	0.62	0.13	113	0.60	0.15
AV-1	44	0.65	0.15	113	0.61	0.19
AV-1 - Baseline	44	0.03	0.11	113	0.01	0.11

(continues)

Table 2.11 (Continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: August 31, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	42	127.88	24.54	111	123.52	28.35
AV-1	42	143.71	41.88	109	127.39	27.16
AV-1 – Baseline	40	19.08	33.73	108	3.82	21.88
Factor VII C (%)[1]						
Baseline	42	127.79	25.16	111	125.07	25.20
AV-1	42	134.45	25.19	109	123.45	27.26
AV-1 – Baseline	40	8.90	19.55	108	-1.48	16.86
Fibrinogen (mg/dl)						
Baseline	42	295.33	55.97	111	300.43	54.95
AV-1	42	287.38	65.65	109	285.02	54.02
AV-1 – Baseline	40	-5.40	58.03	108	-13.99	49.10
Hormones / Other						
Glucose (mg/dl)						
Baseline	44	106.11	29.75	113	102.14	24.70
AV-1	44	105.75	36.70	113	101.22	22.91
AV-1 – Baseline	44	-0.36	12.65	113	-0.92	12.16
Insulin (μIU/ml)						
Baseline	43	12.39	8.58	108	10.53	7.84
AV-1	43	11.67	9.56	108	10.10	7.03
AV-1 – Baseline	42	-0.91	5.60	107	-0.43	5.33

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.11 (Continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: August 31, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	44	178.18	88.75	113	148.58	74.12
AV-1	44	196.43	103.00	112	160.96	103.09
AV-1 – Baseline	44	18.25	80.11	112	12.00	80.72
Total Cholesterol (mg/dl)						
Baseline	44	235.02	32.96	113	222.98	34.15
AV-1	44	220.20	34.17	112	211.75	32.48
AV-1 – Baseline	44	-14.82	22.10	112	-10.92	26.78
LDL-C (mg/dl)						
Baseline	42	139.50	32.14	112	132.72	31.02
AV-1	43	118.77	36.40	109	120.61	30.10
AV-1 – Baseline	41	-22.61	28.73	109	-12.96	27.33
HDL-C (mg/dl)						
Baseline	44	60.11	17.87	113	59.88	15.93
AV-1	44	64.00	18.55	112	60.29	15.84
AV-1 – Baseline	44	3.89	8.39	112	0.88	8.49
HDL-2 (mg/dl)						
Baseline	43	18.58	9.69	112	19.03	8.60
AV-1	43	20.49	9.78	109	20.07	8.61
AV-1 – Baseline	42	1.62	6.58	109	1.32	4.52
HDL-3 (mg/dl)						
Baseline	43	41.19	9.42	112	40.61	8.37
AV-1	43	43.56	11.38	110	40.15	7.98
AV-1 – Baseline	42	1.98	5.95	110	-0.39	5.94
Lp(a) (mg/dl)						
Baseline	44	21.43	14.82	112	20.03	19.45
AV-1	44	16.75	14.85	112	17.03	17.70
AV-1 – Baseline	44	-4.68	7.89	111	-3.04	12.22

Table 2.11 (Continued)
Blood Specimen Analysis: Black/African American Women

Data as of: August 31, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	332	0.07	0.08	255	0.06	0.06
AV-1	330	0.06	0.08	254	0.06	0.07
AV-1 - Baseline	330	0.00	0.06	254	0.00	0.05
Beta-Carotene (µg/ml)						
Baseline	331	0.36	0.38	255	0.31	0.26
AV-1	329	0.35	0.36	255	0.29	0.26
AV-1 – Baseline	329	-0.01	0.20	255	-0.02	0.19
Alpha-tocopherol (µg/ml)						
Baseline	332	14.29	6.30	255	14.54	6.47
AV-1	330	14.38	5.42	255	14.60	6.50
AV-1 – Baseline	330	0.12	5.10	255	0.06	5.08
Gamma-tocopherol (µg/ml)						
Baseline	332	2.49	1.37	255	2.49	1.41
AV-1	330	2.32	1.38	255	2.29	1.32
AV-1 – Baseline	330	-0.18	0.91	255	-0.20	0.95
Beta-Cryptoxanthine (µg/ml)						
Baseline	332	0.09	0.06	255	0.09	0.06
AV-1	330	0.09	0.07	255	0.08	0.06
AV-1 - Baseline	330	0.00	0.06	255	0.00	0.06
Lycopene (µg/ml)						
Baseline	332	0.38	0.21	255	0.39	0.21
AV-1	330	0.38	0.21	255	0.37	0.21
AV-1 - Baseline	330	0.00	0.18	255	-0.02	0.19
Lutein and Zeaxanthin (µg/ml)						
Baseline	332	0.25	0.13	255	0.23	0.11
AV-1	330	0.25	0.12	255	0.24	0.11
AV-1 - Baseline	330	0.00	0.08	255	0.02	0.08
Retinol (µg/ml)						
Baseline	332	0.56	0.16	255	0.56	0.16
AV-1	330	0.57	0.15	255	0.57	0.15
AV-1 - Baseline	330	0.01	0.10	255	0.01	0.08

(continues)

Table 2.11 (Continued)
Blood Specimen Analysis: Black/African American Women

Data as of: August 31, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	324	113.42	23.27	243	113.85	26.63
AV-1	321	119.04	28.64	246	118.21	30.64
AV-1 – Baseline	314	5.70	20.64	236	4.69	18.61
Factor VII C (%)[1]						
Baseline	314	117.74	27.05	237	117.12	29.48
AV-1	317	118.60	26.68	245	115.49	27.54
AV-1 – Baseline	300	1.44	19.10	229	-1.91	20.60
Fibrinogen (mg/dl)						
Baseline	324	326.07	64.58	243	319.74	67.50
AV-1	320	325.38	67.19	246	314.46	63.74
AV-1 – Baseline	313	-1.76	52.35	236	-4.91	47.22
Hormones / Other						
Glucose (mg/dl)						
Baseline	331	110.79	42.04	255	108.86	39.46
AV-1	330	108.82	41.13	254	109.60	41.38
AV-1 – Baseline	329	-1.12	36.94	254	0.64	26.19
Insulin (μIU/ml)						
Baseline	324	14.97	14.10	252	13.44	8.51
AV-1	328	14.41	13.60	254	13.23	7.82
AV-1 – Baseline	320	-0.83	8.40	251	-0.14	6.25

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.11 (Continued)
Blood Specimen Analysis: Black/African American Women

Data as of: August 31, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	332	118.05	51.48	255	120.51	62.49
AV-1	330	122.08	50.54	255	118.22	54.10
AV-1 – Baseline	330	4.57	38.61	255	-2.29	39.97
Total Cholesterol (mg/dl)						
Baseline	332	225.42	41.85	255	221.56	42.37
AV-1	330	220.17	40.92	255	214.84	38.62
AV-1 – Baseline	330	-4.88	29.25	255	-6.73	24.97
LDL-C (mg/dl)						
Baseline	331	144.73	39.83	253	140.37	39.02
AV-1	330	134.49	39.06	253	132.55	37.84
AV-1 – Baseline	330	-9.95	27.53	252	-8.51	22.51
HDL-C (mg/dl)						
Baseline	331	57.08	13.14	254	56.72	13.42
AV-1	330	61.21	15.47	255	59.21	14.52
AV-1 – Baseline	330	4.11	9.70	254	2.47	8.04
HDL-2 (mg/dl)						
Baseline	329	17.91	6.96	248	17.28	7.26
AV-1	328	20.19	8.50	254	18.88	8.25
AV-1 – Baseline	326	2.24	5.49	248	1.59	5.17
HDL-3 (mg/dl)						
Baseline	329	39.17	7.82	248	39.40	7.30
AV-1	330	41.08	8.90	254	40.21	7.74
AV-1 – Baseline	327	1.85	5.82	248	0.76	4.85
Lp(a) (mg/dl)						
Baseline	326	39.34	31.54	249	38.80	29.53
AV-1	328	38.50	31.58	254	37.27	28.10
AV-1 – Baseline	324	-1.01	12.71	249	-2.11	10.94

Table 2.11 (Continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: August 31, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	144	0.10	0.12	183	0.10	0.10
AV-1	143	0.08	0.06	183	0.09	0.07
AV-1 - Baseline	143	-0.02	0.11	183	-0.01	0.08
Beta-Carotene (µg/ml)						
Baseline	144	0.34	0.53	183	0.32	0.29
AV-1	143	0.27	0.26	183	0.28	0.22
AV-1 – Baseline	143	-0.07	0.39	183	-0.05	0.25
Alpha-tocopherol (µg/ml)						
Baseline	144	15.52	7.52	183	15.82	6.51
AV-1	143	16.80	7.51	183	16.58	7.44
AV-1 – Baseline	143	1.28	6.03	183	0.76	5.12
Gamma-tocopherol (µg/ml)						
Baseline	144	2.28	1.38	183	2.21	1.40
AV-1	143	2.07	1.36	183	1.93	1.29
AV-1 – Baseline	143	-0.21	0.98	183	-0.28	0.95
Beta-Cryptoxanthine (µg/ml)						
Baseline	144	0.13	0.18	183	0.13	0.12
AV-1	143	0.11	0.11	183	0.12	0.11
AV-1 - Baseline	143	-0.02	0.15	183	-0.01	0.09
Lycopene (µg/ml)						
Baseline	144	0.40	0.19	183	0.46	0.21
AV-1	143	0.37	0.18	183	0.40	0.19
AV-1 - Baseline	143	-0.03	0.15	183	-0.05	0.17
Lutein and Zeaxanthin (µg/ml)						
Baseline	144	0.20	0.09	183	0.23	0.11
AV-1	143	0.20	0.09	183	0.22	0.11
AV-1 - Baseline	143	0.00	0.06	183	-0.01	0.08
Retinol (µg/ml)						
Baseline	144	0.52	0.13	183	0.56	0.14
AV-1	143	0.55	0.13	183	0.56	0.15
AV-1 - Baseline	143	0.02	0.08	183	0.00	0.09

(continues)

Table 2.11 (Continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: August 31, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	137	121.37	24.97	172	123.84	28.35
AV-1	130	128.44	26.54	177	128.99	28.61
AV-1 – Baseline	123	9.42	24.53	168	4.43	22.81
Factor VII C (%)[1]						
Baseline	132	124.00	28.43	165	123.38	26.97
AV-1	127	126.90	24.79	172	123.38	25.98
AV-1 – Baseline	117	3.45	26.60	158	-0.80	19.87
Fibrinogen (mg/dl)						
Baseline	137	318.08	67.20	172	319.57	66.56
AV-1	130	309.63	60.54	176	315.19	61.24
AV-1 – Baseline	123	-5.77	54.43	167	-6.71	52.31
Hormones / Other						
Glucose (mg/dl)						
Baseline	142	103.13	27.63	183	105.79	31.05
AV-1	143	105.90	36.43	183	104.69	30.31
AV-1 – Baseline	141	3.00	23.70	183	-1.09	17.83
Insulin (µIU/ml)						
Baseline	141	13.64	8.86	182	13.62	7.98
AV-1	141	13.37	8.13	180	13.21	6.66
AV-1 – Baseline	139	-0.35	6.26	180	-0.41	6.00

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.11 (Continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: August 31, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	144	159.47	69.02	183	167.25	83.55
AV-1	143	168.32	68.62	183	181.46	123.50
AV-1 – Baseline	143	8.41	51.74	183	14.21	94.14
Total Cholesterol (mg/dl)						
Baseline	144	219.06	39.03	183	226.67	38.14
AV-1	143	212.62	35.36	183	214.91	35.38
AV-1 – Baseline	143	-6.18	27.27	183	-11.76	23.84
LDL-C (mg/dl)						
Baseline	142	132.16	33.53	179	139.96	35.55
AV-1	142	122.48	31.79	176	126.95	33.86
AV-1 – Baseline	140	-9.51	26.15	174	-14.01	24.32
HDL-C (mg/dl)						
Baseline	143	54.41	13.02	183	53.18	12.44
AV-1	143	57.03	14.85	183	53.83	13.08
AV-1 – Baseline	142	2.61	9.43	183	0.64	7.14
HDL-2 (mg/dl)						
Baseline	143	16.50	6.70	180	15.76	6.81
AV-1	142	17.97	7.91	183	16.63	6.75
AV-1 – Baseline	141	1.40	5.24	180	0.89	4.43
HDL-3 (mg/dl)						
Baseline	143	37.92	7.48	180	37.34	7.26
AV-1	142	39.04	8.08	183	37.20	7.59
AV-1 – Baseline	141	1.20	5.44	180	-0.31	4.77
Lp(a) (mg/dl)						
Baseline	142	16.87	18.20	183	21.43	22.84
AV-1	140	16.29	17.96	182	19.74	21.08
AV-1 – Baseline	139	-0.74	7.24	182	-1.79	10.78

Table 2.11 (Continued)
Blood Specimen Analysis: White Women

Data as of: August 31, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	423	0.07	0.06	715	0.09	0.08
AV-1	423	0.06	0.05	715	0.08	0.08
AV-1 - Baseline	421	-0.01	0.05	715	-0.01	0.06
Beta-Carotene (µg/ml)						
Baseline	423	0.27	0.20	715	0.35	0.34
AV-1	423	0.24	0.22	715	0.31	0.31
AV-1 – Baseline	421	-0.02	0.20	715	-0.04	0.21
Alpha-tocopherol (µg/ml)						
Baseline	423	16.28	7.08	715	16.55	7.91
AV-1	423	18.14	9.25	715	17.06	7.36
AV-1 – Baseline	421	1.86	6.43	715	0.51	5.81
Gamma-tocopherol (µg/ml)						
Baseline	423	2.53	1.75	715	2.20	1.38
AV-1	423	2.21	1.92	715	1.80	1.22
AV-1 – Baseline	421	-0.32	1.16	715	-0.40	0.92
Beta-Cryptoxanthine (µg/ml)						
Baseline	423	0.08	0.05	715	0.09	0.07
AV-1	423	0.07	0.06	714	0.08	0.07
AV-1 - Baseline	421	0.00	0.04	714	-0.01	0.06
Lycopene (µg/ml)						
Baseline	423	0.40	0.20	715	0.41	0.19
AV-1	423	0.39	0.19	715	0.40	0.19
AV-1 - Baseline	421	-0.01	0.17	715	-0.01	0.17
Lutein and Zeaxanthin (µg/ml)						
Baseline	423	0.20	0.09	715	0.21	0.09
AV-1	423	0.20	0.10	715	0.21	0.09
AV-1 - Baseline	421	0.00	0.06	715	0.00	0.06
Retinol (µg/ml)						
Baseline	423	0.61	0.14	715	0.61	0.15
AV-1	423	0.64	0.15	715	0.62	0.14
AV-1 - Baseline	421	0.03	0.11	715	0.01	0.10

(continues)

Table 2.11 (Continued)
Blood Specimen Analysis: White Women

Data as of: August 31, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	412	131.78	29.41	695	125.19	28.64
AV-1	401	142.28	35.43	689	131.56	31.25
AV-1 – Baseline	393	10.85	25.78	673	6.12	23.14
Factor VII C (%)[1]						
Baseline	409	131.61	26.97	689	126.11	26.78
AV-1	397	138.84	32.33	685	126.34	27.93
AV-1 – Baseline	387	6.76	24.52	663	-0.38	22.27
Fibrinogen (mg/dl)						
Baseline	410	309.95	62.92	693	304.73	57.69
AV-1	400	298.43	60.01	687	296.00	57.78
AV-1 – Baseline	390	-12.90	51.92	669	-8.35	53.74
Hormones / Other						
Glucose (mg/dl)						
Baseline	423	104.86	34.35	711	99.36	24.56
AV-1	421	101.84	29.97	713	97.13	20.57
AV-1 – Baseline	419	-3.38	18.13	709	-2.23	15.83
Insulin (μIU/ml)						
Baseline	414	12.39	7.13	685	11.15	6.58
AV-1	413	11.71	6.99	682	11.09	7.13
AV-1 – Baseline	403	-0.73	5.64	662	-0.04	5.52

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.11 (Continued)
Blood Specimen Analysis: White Women

Data as of: August 31, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	423	167.57	107.26	714	147.66	74.11
AV-1	421	181.95	142.53	715	150.16	70.15
AV-1 – Baseline	419	14.65	77.56	714	2.42	53.74
Total Cholesterol (mg/dl)						
Baseline	423	230.82	41.06	714	225.59	36.25
AV-1	421	224.84	40.63	715	216.51	34.84
AV-1 – Baseline	419	-5.91	30.41	714	-9.10	28.90
LDL-C (mg/dl)						
Baseline	410	142.36	36.92	700	138.75	32.09
AV-1	406	128.64	35.32	706	126.81	31.61
AV-1 – Baseline	399	-13.63	27.44	696	-11.68	26.05
HDL-C (mg/dl)						
Baseline	421	55.87	14.78	710	57.28	14.61
AV-1	419	60.17	17.10	715	59.68	15.03
AV-1 – Baseline	416	4.25	9.38	710	2.39	8.22
HDL-2 (mg/dl)						
Baseline	400	17.36	7.72	684	18.15	7.72
AV-1	402	19.51	8.90	687	19.44	8.19
AV-1 – Baseline	384	2.09	4.97	661	1.17	4.65
HDL-3 (mg/dl)						
Baseline	400	38.66	8.52	684	39.06	8.24
AV-1	402	41.00	9.63	687	40.32	8.28
AV-1 – Baseline	384	2.21	5.79	661	1.20	5.28
Lp(a) (mg/dl)						
Baseline	414	25.46	25.75	702	26.22	27.99
AV-1	413	24.38	26.42	704	24.22	27.73
AV-1 – Baseline	405	-0.99	10.75	693	-1.84	10.66

Table 2.11 (Continued)
Blood Specimen Analysis: Other/Unspecified Women

Data as of: August 31, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	23	0.10	0.06	28	0.11	0.14
AV-1	23	0.10	0.09	29	0.09	0.10
AV-1 - Baseline	23	0.00	0.07	28	-0.03	0.05
Beta-Carotene (µg/ml)						
Baseline	23	0.37	0.32	28	0.43	0.47
AV-1	23	0.35	0.25	29	0.35	0.31
AV-1 – Baseline	23	-0.03	0.16	28	-0.07	0.29
Alpha-tocopherol (µg/ml)						
Baseline	23	17.97	8.44	28	17.07	7.90
AV-1	23	18.94	11.06	29	17.21	6.22
AV-1 – Baseline	23	0.97	5.11	28	0.09	5.64
Gamma-tocopherol (µg/ml)						
Baseline	23	2.14	1.09	28	1.86	1.08
AV-1	23	2.00	0.87	29	1.73	1.06
AV-1 – Baseline	23	-0.14	0.99	28	-0.08	0.70
Beta-Cryptoxanthine (µg/ml)						
Baseline	23	0.09	0.08	28	0.11	0.13
AV-1	23	0.11	0.07	29	0.08	0.06
AV-1 - Baseline	23	0.01	0.05	28	-0.02	0.08
Lycopene (µg/ml)						
Baseline	23	0.49	0.21	28	0.33	0.21
AV-1	23	0.44	0.23	29	0.33	0.22
AV-1 - Baseline	23	-0.06	0.24	28	0.00	0.16
Lutein and Zeaxanthin (µg/ml)						
Baseline	23	0.20	0.10	28	0.20	0.14
AV-1	23	0.20	0.11	29	0.22	0.12
AV-1 - Baseline	23	-0.01	0.07	28	0.01	0.10
Retinol (µg/ml)						
Baseline	23	0.59	0.15	28	0.59	0.14
AV-1	23	0.64	0.19	29	0.60	0.13
AV-1 - Baseline	23	0.06	0.13	28	0.00	0.12

(continues)

Table 2.11 (Continued)
Blood Specimen Analysis: Other/Unspecified Women

Data as of: August 31, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	23	124.57	23.33	29	122.21	22.84
AV-1	23	133.00	26.98	28	130.21	27.60
AV-1 – Baseline	23	8.43	26.66	28	8.82	16.06
Factor VII C (%)[1]						
Baseline	22	124.64	23.74	29	124.10	22.73
AV-1	23	130.57	20.25	28	127.11	27.36
AV-1 – Baseline	22	7.41	19.63	28	3.71	18.73
Fibrinogen (mg/dl)						
Baseline	23	318.52	56.73	29	331.62	73.29
AV-1	23	294.04	64.72	28	307.32	59.63
AV-1 – Baseline	23	-24.48	53.87	28	-23.04	51.03
Hormones / Other						
Glucose (mg/dl)						
Baseline	23	98.87	20.65	29	102.41	28.62
AV-1	23	103.04	28.07	29	99.59	19.11
AV-1 – Baseline	23	4.17	14.54	29	-2.83	14.46
Insulin (μIU/ml)						
Baseline	23	10.30	6.84	29	10.86	5.13
AV-1	23	10.90	7.41	29	10.97	6.59
AV-1 – Baseline	23	0.61	6.25	29	0.11	3.45

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.11 (Continued)
Blood Specimen Analysis: Other/Unspecified Women

Data as of: August 31, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	23	156.57	92.42	29	159.52	77.01
AV-1	23	168.13	68.18	29	161.72	75.02
AV-1 – Baseline	23	11.57	62.43	29	2.21	38.74
Total Cholesterol (mg/dl)						
Baseline	23	241.43	42.05	29	221.52	36.60
AV-1	23	236.48	36.92	29	220.34	38.73
AV-1 – Baseline	23	-4.96	28.61	29	-1.17	29.84
LDL-C (mg/dl)						
Baseline	22	155.55	37.38	29	135.24	34.16
AV-1	23	143.65	35.75	29	132.62	41.10
AV-1 – Baseline	22	-10.27	23.25	29	-2.62	29.46
HDL-C (mg/dl)						
Baseline	23	54.57	12.33	29	54.38	15.41
AV-1	23	59.17	13.34	29	55.31	15.06
AV-1 – Baseline	23	4.61	7.45	29	0.93	4.78
HDL-2 (mg/dl)						
Baseline	23	16.48	6.93	28	16.14	8.54
AV-1	22	18.73	7.25	29	17.00	9.21
AV-1 – Baseline	22	1.91	5.08	28	0.57	4.14
HDL-3 (mg/dl)						
Baseline	23	38.09	6.53	28	37.71	8.05
AV-1	22	41.50	6.84	29	38.31	7.28
AV-1 – Baseline	22	3.00	4.86	28	0.18	3.38
Lp(a) (mg/dl)						
Baseline	23	20.22	23.07	29	26.55	27.07
AV-1	22	20.23	23.22	29	23.00	19.88
AV-1 – Baseline	22	-0.55	3.20	29	-3.55	15.82

Table 2.12
Bone Mineral Density[1] Analysis: HRT Participants

Data as of: August 31, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan						
Baseline	938	1.01	0.11	1025	0.99	0.10
AV1	843	1.01	0.11	928	1.00	0.10
AV3	773	1.03	0.12	856	1.02	0.10
AV6	296	1.03	0.12	324	1.02	0.11
AV1 % Change from baseline BMD[2]	841	0.43	2.79	925	0.26	2.35
AV3 % Change from baseline BMD[3]	771	2.16	4.40	851	1.99	3.81
AV6 % Change from baseline BMD[4]	294	2.23	5.10	322	2.79	5.13
Spine Scan						
Baseline	910	0.97	0.16	998	0.95	0.16
AV1	822	0.99	0.16	900	0.97	0.16
AV3	760	1.00	0.17	839	0.99	0.17
AV6	295	1.01	0.17	322	0.99	0.17
AV1 % Change from baseline BMD[2]	819	1.91	4.57	897	2.07	4.34
AV3 % Change from baseline BMD[3]	757	3.55	6.18	834	4.09	6.06
AV6 % Change from baseline BMD[4]	292	4.09	7.51	321	5.25	7.89
Hip Scan						
Baseline	934	0.86	0.14	1024	0.84	0.13
AV1	841	0.86	0.14	927	0.84	0.13
AV3	774	0.88	0.15	860	0.86	0.14
AV6	300	0.88	0.14	333	0.86	0.13
AV1 % Change from baseline BMD[2]	838	0.72	3.31	924	0.63	3.17
AV3 % Change from baseline BMD[3]	768	2.21	4.86	854	2.17	4.78
AV6 % Change from baseline BMD[4]	297	0.85	5.60	327	1.65	5.62

[1] Measured in (g/cm^2).
[2] AV1 % Change from baseline BMD is defined as ((AV1-Baseline)/Baseline)x100.
[3] AV3 % Change from baseline BMD is defined as ((AV3-Baseline)/Baseline)x100.
[4] AV6 % Change from baseline BMD is defined as ((AV6-Baseline)/Baseline)x100.

Table 2.13
Bone Mineral Density[1] Analysis: HRT Participants by Race/Ethnicity

Data as of: August 31, 2001

	Black/African American						Hispanic/Latino						White					
	Without Uterus			With Uterus			Without Uterus			With Uterus			Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan																		
Baseline	174	1.06	0.10	99	1.08	0.11	66	1.03	0.10	61	1.02	0.11	686	0.99	0.10	843	0.98	0.09
AV1	153	1.07	0.11	86	1.08	0.11	44	1.04	0.10	50	1.03	0.10	635	1.00	0.10	775	0.99	0.09
AV3	150	1.09	0.11	87	1.10	0.12	51	1.05	0.12	45	1.06	0.11	564	1.01	0.12	707	1.00	0.10
AV6	56	1.08	0.11	33	1.10	0.12	12	1.10	0.14	9	1.14	0.19	223	1.02	0.11	276	1.01	0.10
AV1 % Change from baseline BMD[2]	153	0.75	2.95	86	0.91	2.86	44	-0.16	2.30	49	-0.07	2.42	633	0.39	2.76	773	0.21	2.27
AV3 % Change from baseline BMD[3]	150	2.06	3.45	87	2.15	3.18	51	1.66	4.58	44	3.15	5.43	562	2.23	4.61	703	1.88	3.77
AV6 % Change from baseline BMD[4]	56	0.50	4.03	33	0.32	4.53	12	7.53	7.00	9	7.25	2.97	221	2.36	4.99	274	2.97	5.17
Spine Scan																		
Baseline	171	1.04	0.15	99	1.08	0.19	65	0.96	0.13	61	0.92	0.14	662	0.95	0.16	816	0.93	0.15
AV1	150	1.05	0.16	86	1.09	0.19	44	0.97	0.11	49	0.95	0.15	617	0.97	0.16	748	0.96	0.16
AV3	147	1.07	0.17	87	1.11	0.20	51	0.95	0.13	45	0.94	0.14	554	0.99	0.17	690	0.97	0.16
AV6	56	1.07	0.17	35	1.13	0.20	12	0.96	0.17	8	0.99	0.22	222	0.99	0.16	273	0.98	0.16
AV1 % Change from baseline BMD[2]	150	1.92	4.39	86	1.75	4.81	44	-0.65	4.45	49	1.71	6.86	614	2.11	4.57	745	2.13	4.09
AV3 % Change from baseline BMD[3]	147	3.43	6.16	87	3.01	6.39	51	-0.31	5.62	44	2.97	7.06	551	3.96	6.09	686	4.30	5.93
AV6 % Change from baseline BMD[4]	56	3.47	7.03	35	1.72	6.82	12	3.44	7.86	8	3.47	9.02	219	4.37	7.68	272	5.73	7.90
Hip Scan																		
Baseline	174	0.96	0.13	98	0.97	0.15	65	0.87	0.11	61	0.84	0.13	683	0.83	0.13	843	0.82	0.12
AV1	153	0.97	0.13	86	0.97	0.14	43	0.87	0.11	50	0.85	0.12	634	0.83	0.13	774	0.83	0.12
AV3	150	0.98	0.14	87	0.99	0.15	50	0.89	0.13	45	0.88	0.13	566	0.85	0.14	711	0.84	0.13
AV6	57	0.96	0.14	34	0.97	0.14	12	0.86	0.17	9	0.87	0.13	226	0.86	0.13	284	0.85	0.12
AV1 % Change from baseline BMD[2]	153	1.16	2.97	86	1.14	3.43	43	0.31	3.62	49	1.09	3.47	631	0.65	3.37	772	0.54	3.13
AV3 % Change from baseline BMD[3]	150	1.87	3.91	87	1.38	3.94	50	2.65	5.36	44	4.47	5.93	560	2.26	5.03	706	2.08	4.77
AV6 % Change from baseline BMD[4]	57	-1.38	5.46	33	-2.36	5.56	12	2.99	6.48	9	2.79	6.11	223	1.34	5.44	279	2.10	5.45

[1] Measured in (g/cm^2).
[2] AV1 % Change from baseline BMD is defined as ((AV1-Baseline)/Baseline)x100.
[3] AV3 % Change from baseline BMD is defined as ((AV3-Baseline)/Baseline)x100.
[4] AV6 % Change from baseline BMD is defined as ((AV6-Baseline)/Baseline)x100.

Table 2.14
Lost-to-Follow-up and Vital Status: HRT Participants by Hysterectomy Status

Data as of: August 31, 2001

	Without Uterus (N=10,739)		With Uterus (N=16,608)		HRT Participants (N=27,347)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	286	2.7	356	2.1	642	2.3
Alive: Current Participation[1]	9786	91.1	15443	93.0	25229	92.3
Alive: Recent Participation[2]	236	2.2	267	1.6	503	1.8
Alive: Past/Unknown Participation[3]	11	0.1	18	0.1	29	0.1
Stopped Follow-Up[4]	225	2.1	292	1.8	517	1.9
Lost to Follow-Up[5]	195	1.8	232	1.4	427	1.6

[1] Participants who have filled in a Form 33 within the last 9 months.
[2] Participants who last filled in a Form 33 between 9 and 18 months ago.
[3] Participiants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.
[5] Participants not in any of the above categories.

Table 2.15

Locally Verified Outcomes (Annualized Percentages) by Age for Hormone Replacement Therapy

Data as of: August 31, 2001

Outcomes	Total	Age 50-54	Age 55-59	Age 60-69	Age 70-79
Number randomized	27347	3425	5407	12365	6150
Mean follow-up (months)	54.2	59.3	56.1	53.1	51.7
Cardiovascular					
CHD[1]	439 (0.36%)	26 (0.15%)	38 (0.15%)	196 (0.36%)	179 (0.68%)
CHD death[2]	101 (0.08%)	6 (0.04%)	9 (0.04%)	38 (0.07%)	48 (0.18%)
Total MI[3]	371 (0.30%)	21 (0.12%)	31 (0.12%)	169 (0.31%)	150 (0.57%)
Clinical MI	362 (0.29%)	20 (0.12%)	31 (0.12%)	162 (0.30%)	149 (0.56%)
Evolving Q-wave MI[4]	21 (0.02%)	2 (0.01%)	1 (<0.01%)	13 (0.02%)	5 (0.02%)
Possible evolving Q-wave MI[4]	82 (0.07%)	6 (0.04%)	9 (0.04%)	36 (0.07%)	31 (0.12%)
Angina	640 (0.52%)	21 (0.12%)	83 (0.33%)	292 (0.53%)	244 (0.92%)
CABG/PTCA	594 (0.48%)	21 (0.12%)	73 (0.29%)	272 (0.50%)	228 (0.86%)
Carotid artery disease	125 (0.10%)	0 (0.00%)	13 (0.05%)	63 (0.12%)	49 (0.19%)
Congestive heart failure	339 (0.27%)	14 (0.08%)	36 (0.14%)	141 (0.26%)	148 (0.56%)
Stroke	344 (0.28%)	10 (0.06%)	38 (0.15%)	152 (0.28%)	144 (0.54%)
Non-disabling stroke	197 (0.16%)	8 (0.05%)	25 (0.10%)	92 (0.17%)	72 (0.27%)
Fatal/disabling stroke	93 (0.08%)	1 (0.01%)	5 (0.02%)	36 (0.07%)	51 (0.19%)
Unknown status from stroke	54 (0.04%)	1 (0.01%)	8 (0.03%)	24 (0.04%)	21 (0.08%)
PVD	97 (0.08%)	5 (0.03%)	9 (0.04%)	46 (0.08%)	37 (0.14%)
DVT	206 (0.17%)	11 (0.07%)	29 (0.11%)	94 (0.17%)	72 (0.27%)
Pulmonary embolism	122 (0.10%)	6 (0.04%)	20 (0.08%)	54 (0.10%)	42 (0.16%)
CHD[1]/Possible evolving Q-wave MI	508 (0.41%)	32 (0.19%)	45 (0.18%)	224 (0.41%)	207 (0.78%)
Coronary disease[5]	1327 (1.08%)	61 (0.36%)	153 (0.61%)	597 (1.09%)	516 (1.95%)
DVT/PE	271 (0.22%)	13 (0.08%)	38 (0.15%)	128 (0.23%)	92 (0.35%)
Total cardiovascular disease	2002 (1.62%)	88 (0.52%)	229 (0.91%)	922 (1.68%)	763 (2.88%)
Cancer					
Breast cancer[6]	449 (0.36%)	47 (0.28%)	71 (0.28%)	228 (0.42%)	103 (0.39%)
Invasive breast cancer	352 (0.29%)	36 (0.21%)	59 (0.23%)	174 (0.32%)	83 (0.31%)
Non-invasive breast cancer	101 (0.08%)	11 (0.07%)	13 (0.05%)	57 (0.10%)	20 (0.08%)
Ovary cancer	44 (0.04%)	1 (0.01%)	7 (0.03%)	25 (0.05%)	11 (0.04%)
Endometrial cancer[7]	38 (0.05%)	0 (0.00%)	5 (0.03%)	20 (0.06%)	13 (0.09%)
Colorectal cancer	175 (0.14%)	9 (0.05%)	19 (0.08%)	88 (0.16%)	59 (0.22%)
Other cancer[8]	600 (0.49%)	45 (0.27%)	78 (0.31%)	279 (0.51%)	198 (0.75%)
Total cancer	1274 (1.03%)	102 (0.60%)	177 (0.70%)	623 (1.14%)	372 (1.41%)
Fractures					
Hip fracture	138 (0.11%)	3 (0.02%)	5 (0.02%)	42 (0.08%)	88 (0.33%)
Vertebral fracture	141 (0.11%)	6 (0.04%)	15 (0.06%)	56 (0.10%)	64 (0.24%)
Other fracture[8]	1840 (1.49%)	211 (1.25%)	288 (1.14%)	870 (1.59%)	471 (1.78%)
Total fracture	2051 (1.66%)	218 (1.29%)	304 (1.20%)	942 (1.72%)	587 (2.22%)
Deaths					
Cardiovascular deaths	197 (0.16%)	8 (0.05%)	16 (0.06%)	76 (0.14%)	97 (0.37%)
Cancer deaths	273 (0.22%)	13 (0.08%)	25 (0.10%)	131 (0.24%)	104 (0.39%)
Deaths: other known cause	89 (0.07%)	8 (0.05%)	13 (0.05%)	33 (0.06%)	35 (0.13%)
Deaths: unknown cause	83 (0.07%)	6 (0.04%)	8 (0.03%)	35 (0.06%)	34 (0.13%)
Deaths: not yet adjudicated	41 (0.03%)	1 (0.01%)	2 (0.01%)	20 (0.04%)	18 (0.07%)
Total death	642 (0.52%)	35 (0.21%)	62 (0.25%)	275 (0.50%)	270 (1.02%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death. It corresponds to what was "CHD (corrected)" in the February 2001 report.
[2] "CHD death" includes definite and possible CHD death. It corresponds to what was "CHD death (corrected)" in the February 2001 report.
[3] "Total MI' includes clinical MI and evolving Q-wave MI.
[4] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[6] Excludes four cases with borderline malignancy.
[7] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[8] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

Table 2.15 (Continued)
Locally Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Hormone Replacement Therapy

Data as of: August 31, 2001

Outcomes	Race/Ethnicity: American Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Other/ Unspecified
Number randomized	130	527	2738	1537	22030	385
Mean follow-up (months)	52.5	50.7	53.6	51.6	54.6	50.1
Cardiovascular						
CHD[1]	3 (0.53%)	5 (0.22%)	40 (0.33%)	15 (0.23%)	369 (0.37%)	7 (0.44%)
CHD death[2]	1 (0.18%)	3 (0.13%)	17 (0.14%)	4 (0.06%)	74 (0.07%)	2 (0.12%)
Total MI[3]	2 (0.35%)	4 (0.18%)	28 (0.23%)	12 (0.18%)	319 (0.32%)	6 (0.37%)
Clinical MI	2 (0.35%)	4 (0.18%)	27 (0.22%)	12 (0.18%)	311 (0.31%)	6 (0.37%)
Evolving Q-wave MI[4]	0 (0.00%)	0 (0.00%)	1 (0.01%)	0 (0.00%)	18 (0.02%)	2 (0.12%)
Possible evolving Q-wave MI[4]	0 (0.00%)	1 (0.04%)	10 (0.08%)	3 (0.05%)	67 (0.07%)	1 (0.06%)
Angina	4 (0.70%)	10 (0.45%)	58 (0.47%)	29 (0.44%)	532 (0.53%)	7 (0.44%)
CABG/PTCA	4 (0.70%)	5 (0.22%)	43 (0.35%)	23 (0.35%)	512 (0.51%)	7 (0.44%)
Carotid artery disease	1 (0.18%)	1 (0.04%)	6 (0.05%)	0 (0.00%)	117 (0.12%)	0 (0.00%)
Congestive heart failure	2 (0.35%)	4 (0.18%)	47 (0.38%)	10 (0.15%)	272 (0.27%)	4 (0.25%)
Stroke	2 (0.35%)	7 (0.31%)	47 (0.38%)	10 (0.15%)	273 (0.27%)	5 (0.31%)
Non-disabling stroke	1 (0.18%)	5 (0.22%)	26 (0.21%)	8 (0.12%)	154 (0.15%)	3 (0.19%)
Fatal/disabling stroke	1 (0.18%)	1 (0.04%)	14 (0.11%)	1 (0.02%)	75 (0.07%)	1 (0.06%)
Unknown status from stroke	0 (0.00%)	1 (0.04%)	7 (0.06%)	1 (0.02%)	44 (0.04%)	1 (0.06%)
PVD	1 (0.18%)	0 (0.00%)	11 (0.09%)	2 (0.03%)	83 (0.08%)	0 (0.00%)
DVT	1 (0.18%)	1 (0.04%)	17 (0.14%)	4 (0.06%)	183 (0.18%)	0 (0.00%)
Pulmonary embolism	3 (0.53%)	1 (0.04%)	10 (0.08%)	1 (0.02%)	107 (0.11%)	0 (0.00%)
CHD[1]/Possible evolving Q-wave MI	3 (0.53%)	6 (0.27%)	47 (0.38%)	18 (0.27%)	426 (0.43%)	8 (0.50%)
Coronary disease[5]	7 (1.23%)	17 (0.76%)	135 (1.10%)	54 (0.82%)	1097 (1.10%)	17 (1.06%)
DVT/PE	4 (0.70%)	1 (0.04%)	22 (0.18%)	4 (0.06%)	240 (0.24%)	0 (0.00%)
Total cardiovascular disease	13 (2.28%)	25 (1.12%)	204 (1.67%)	67 (1.01%)	1671 (1.67%)	22 (1.37%)
Cancer						
Breast cancer[6]	0 (0.00%)	10 (0.45%)	35 (0.29%)	14 (0.21%)	389 (0.39%)	1 (0.06%)
Invasive breast cancer	0 (0.00%)	8 (0.36%)	29 (0.24%)	8 (0.12%)	306 (0.31%)	1 (0.06%)
Non-invasive breast cancer	0 (0.00%)	2 (0.09%)	7 (0.06%)	6 (0.09%)	86 (0.09%)	0 (0.00%)
Ovary cancer	0 (0.00%)	0 (0.00%)	3 (0.02%)	0 (0.00%)	41 (0.04%)	0 (0.00%)
Endometrial cancer[7]	1 (0.41%)	0 (0.00%)	0 (0.00%)	1 (0.03%)	36 (0.06%)	0 (0.00%)
Colorectal cancer	0 (0.00%)	6 (0.27%)	19 (0.16%)	11 (0.17%)	137 (0.14%)	2 (0.12%)
Other cancer[8]	3 (0.53%)	12 (0.54%)	51 (0.42%)	21 (0.32%)	505 (0.50%)	8 (0.50%)
Total cancer	4 (0.70%)	28 (1.26%)	105 (0.86%)	45 (0.68%)	1082 (1.08%)	10 (0.62%)
Fractures						
Hip fracture	0 (0.00%)	1 (0.04%)	4 (0.03%)	2 (0.03%)	131 (0.13%)	0 (0.00%)
Vertebral fracture	0 (0.00%)	2 (0.09%)	1 (0.01%)	1 (0.02%)	135 (0.13%)	2 (0.12%)
Other fracture[8]	8 (1.41%)	26 (1.17%)	93 (0.76%)	63 (0.95%)	1631 (1.63%)	19 (1.18%)
Total fracture	8 (1.41%)	28 (1.26%)	98 (0.80%)	64 (0.97%)	1833 (1.83%)	20 (1.24%)
Deaths						
Cardiovascular deaths	1 (0.18%)	4 (0.18%)	33 (0.27%)	4 (0.06%)	152 (0.15%)	3 (0.19%)
Cancer deaths	1 (0.18%)	10 (0.45%)	24 (0.20%)	6 (0.09%)	229 (0.23%)	3 (0.19%)
Deaths: other known cause	2 (0.35%)	1 (0.04%)	11 (0.09%)	0 (0.00%)	75 (0.07%)	0 (0.00%)
Deaths: unknown cause	1 (0.18%)	1 (0.04%)	11 (0.09%)	2 (0.03%)	66 (0.07%)	2 (0.12%)
Deaths: not yet adjudicated	0 (0.00%)	1 (0.04%)	6 (0.05%)	1 (0.02%)	32 (0.03%)	1 (0.06%)
Total death	5 (0.88%)	16 (0.72%)	79 (0.65%)	12 (0.18%)	522 (0.52%)	8 (0.50%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death. It corresponds to what was "CHD (corrected)" in the February 2001 report.
[2] "CHD death" includes definite and possible CHD death. It corresponds to what was "CHD death (corrected)" in the February 2001 report.
[3] "Total MI" includes clinical MI and evolving Q-wave MI.
[4] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[6] Excludes four cases with borderline malignancy.
[7] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[8] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

Table 2.16
Locally Verified Outcomes (Annualized Percentages) for HRT Participants Without and With Uterus

Data as of: August 31, 2001

Outcomes	Without Uterus		With Uterus	
Number randomized	10739		16608	
Mean follow-up (months)	54.1		54.2	
Cardiovascular				
CHD[1]	193	(0.40%)	246	(0.33%)
CHD death[2]	51	(0.11%)	50	(0.07%)
Total MI[3]	159	(0.33%)	212	(0.28%)
Clinical MI	154	(0.32%)	208	(0.28%)
Evolving Q-wave MI[4]	9	(0.02%)	12	(0.02%)
Possible evolving Q-wave MI[4]	30	(0.06%)	52	(0.07%)
Angina	345	(0.71%)	295	(0.39%)
CABG/PTCA	290	(0.60%)	304	(0.41%)
Carotid artery disease	65	(0.13%)	60	(0.08%)
Congestive heart failure	189	(0.39%)	150	(0.20%)
Stroke	165	(0.34%)	179	(0.24%)
Non-disabling stroke	96	(0.20%)	101	(0.13%)
Fatal/disabling stroke	39	(0.08%)	54	(0.07%)
Unknown status from stroke	30	(0.06%)	24	(0.03%)
PVD	48	(0.10%)	49	(0.07%)
DVT	65	(0.13%)	141	(0.19%)
Pulmonary embolism	35	(0.07%)	87	(0.12%)
CHD[1]/Possible evolving Q-wave MI	216	(0.45%)	292	(0.39%)
Coronary disease[5]	657	(1.36%)	670	(0.89%)
DVT/PE	84	(0.17%)	187	(0.25%)
Total cardiovascular disease	947	(1.95%)	1055	(1.41%)
Cancer				
Breast cancer[6]	156	(0.32%)	293	(0.39%)
Invasive breast cancer	117	(0.24%)	235	(0.31%)
Non-invasive breast cancer	40	(0.08%)	61	(0.08%)
Ovary cancer	13	(0.03%)	31	(0.04%)
Endometrial cancer	0	N/A	38	(0.05%)
Colorectal cancer	84	(0.17%)	91	(0.12%)
Other cancer[7]	228	(0.47%)	372	(0.50%)
Total cancer	473	(0.98%)	801	(1.07%)
Fractures				
Hip fracture	49	(0.10%)	89	(0.12%)
Vertebral fracture	52	(0.11%)	89	(0.12%)
Other fracture[7]	715	(1.48%)	1125	(1.50%)
Total fracture	789	(1.63%)	1262	(1.68%)
Deaths				
Cardiovascular deaths	95	(0.20%)	102	(0.14%)
Cancer deaths	122	(0.25%)	151	(0.20%)
Deaths: other known cause	34	(0.07%)	55	(0.07%)
Deaths: unknown cause	35	(0.07%)	48	(0.06%)
Deaths: not yet adjudicated	13	(0.03%)	28	(0.04%)
Total death	286	(0.59%)	356	(0.47%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death. It corresponds to what was "CHD (corrected)" in the February 2001 report.
[2] "CHD death" includes definite and possible CHD death. It corresponds to what was "CHD death (corrected)" in the February 2001 report.
[3] "Total MI" includes clinical MI and evolving Q-wave MI.
[4] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[6] Excludes four cases with borderline malignancy.
[7] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

Table 2.17
Frequency (%)[1] of Various Subcategories of Stroke Diagnosis: HRT Participants

Data as of: August 31, 2001

	Without Uterus		With Uterus	
Number randomized	10739		16608	
Stroke Diagnosis				
Subarachoid hemorrhage	8	4.8%	9	5.0%
Intracerebral hemorrhage	20	12.1%	22	12.3%
Other intracranial hemorrhage	2	1.2%	0	0.0%
Occlusion of cerebral arteries with infarction	92	55.8%	106	59.2%
Acute cerebrovascular disease	31	18.8%	27	15.1%
Central nervous system complications	8	4.8%	7	3.9%
Report of cerebrovascular death only	4	2.4%	7	3.9%
Missing	0	0.0%	1	0.6%
Total	165	100%	179	100%

[1] Percentages are relative to the total number of stroke diagnoses.

Table 2.18
Frequency (%)[1] of Disability Levels Following Stroke – Glasgow Scale: HRT Participants

Data as of: August 31, 2001

	Without Uterus		With Uterus	
Number randomized	10739		16608	
Glasgow scale				
Good recovery	53	32.1%	54	30.2%
Moderately disabled	44	26.7%	50	27.9%
Severely disabled	14	8.5%	22	12.3%
Vegetative survival	0	0.0%	4	2.2%
Death or death within 1 month	24	14.5%	24	13.4%
Unable to categorize stroke	9	5.5%	9	5.0%
Not yet categorized	21	12.7%	16	8.9%
Total	165	100%	179	100%

[1] Percentages are relative to the total number of stroke diagnoses.

Table 2.19
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for HRT Participants who did not report a prevalent condition at baseline

Data as of: August 31, 2001

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	27347	3425	5407	12365	6150
Mean follow-up (months)	54.2	59.3	56.1	53.1	51.7
Hospitalizations					
Ever	9178 (7.44%)	822 (4.86%)	1436 (5.68%)	4233 (7.73%)	2687 (10.15%)
Two or more	3929 (3.18%)	309 (1.83%)	555 (2.20%)	1801 (3.29%)	1264 (4.77%)
Other					
Diabetes (treated)	1211 (1.04%)	167 (1.03%)	244 (1.02%)	540 (1.05%)	260 (1.04%)
Gallbladder disease[1]	1244 (1.21%)	164 (1.12%)	268 (1.24%)	584 (1.29%)	228 (1.06%)
Hysterectomy	388 (0.52%)	30 (0.30%)	69 (0.42%)	198 (0.59%)	91 (0.60%)
Glaucoma	1672 (1.41%)	140 (0.84%)	272 (1.10%)	798 (1.52%)	462 (1.88%)
Osteoporosis	3324 (2.84%)	215 (1.29%)	466 (1.90%)	1598 (3.08%)	1045 (4.37%)
Osteoarthritis[2]	2870 (3.81%)	345 (2.75%)	564 (3.26%)	1315 (4.08%)	646 (4.84%)
Rheumatoid arthritis	989 (0.84%)	132 (0.81%)	217 (0.89%)	422 (0.81%)	218 (0.87%)
Intestinal polyps	1944 (1.69%)	187 (1.14%)	317 (1.31%)	1008 (1.98%)	432 (1.84%)
Lupus	162 (0.13%)	22 (0.13%)	34 (0.13%)	79 (0.14%)	27 (0.10%)
Kidney stones[2]	360 (0.38%)	39 (0.32%)	66 (0.35%)	172 (0.41%)	83 (0.40%)
Cataracts[2]	4914 (5.93%)	223 (1.82%)	635 (3.40%)	2627 (6.95%)	1429 (10.10%)
Pills for hypertension	4365 (4.98%)	480 (3.52%)	843 (4.33%)	1960 (5.16%)	1082 (6.53%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Other/ Unspecified
Number randomized	130	527	2738	1537	22030	385
Mean follow-up (months)	52.5	50.7	53.6	51.6	54.6	50.1
Hospitalizations						
Ever	46 (8.08%)	109 (4.89%)	947 (7.74%)	396 (6.00%)	7572 (7.56%)	108 (6.72%)
Two or more	24 (4.22%)	38 (1.71%)	418 (3.42%)	139 (2.10%)	3277 (3.27%)	33 (2.05%)
Other						
Diabetes (treated)	9 (1.84%)	28 (1.38%)	215 (2.01%)	114 (1.88%)	830 (0.87%)	15 (1.00%)
Gallbladder disease[1]	8 (1.84%)	18 (0.89%)	111 (1.01%)	68 (1.38%)	1024 (1.23%)	15 (1.14%)
Hysterectomy	2 (0.83%)	1 (0.07%)	19 (0.38%)	14 (0.37%)	348 (0.55%)	4 (0.41%)
Glaucoma	8 (1.50%)	33 (1.54%)	219 (1.94%)	98 (1.54%)	1292 (1.34%)	22 (1.47%)
Osteoporosis	17 (3.17%)	75 (3.50%)	154 (1.31%)	153 (2.49%)	2872 (3.03%)	53 (3.48%)
Osteoarthritis[2]	18 (4.69%)	53 (3.42%)	305 (4.17%)	210 (4.64%)	2235 (3.69%)	49 (4.78%)
Rheumatoid arthritis	6 (1.20%)	21 (0.99%)	169 (1.51%)	138 (2.20%)	638 (0.66%)	17 (1.12%)
Intestinal polyps	6 (1.14%)	26 (1.27%)	185 (1.62%)	97 (1.53%)	1616 (1.73%)	14 (0.94%)
Lupus	0 (0.00%)	3 (0.13%)	20 (0.16%)	13 (0.20%)	126 (0.13%)	0 (0.00%)
Kidney stones[2]	3 (0.74%)	12 (0.69%)	35 (0.38%)	32 (0.64%)	277 (0.36%)	1 (0.08%)
Cataracts[2]	23 (5.84%)	80 (5.25%)	429 (5.22%)	259 (5.36%)	4064 (6.08%)	59 (5.40%)
Pills for hypertension	25 (6.23%)	82 (5.27%)	425 (7.03%)	258 (5.21%)	3522 (4.78%)	53 (5.09%)

[1] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[2] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 2.20
Sensitivity of HRT Study Power to Adherence and Incidence Rate Assumptions[1]

Outcome	Year	Intervention Effect[2] (%)	Percentage of Cases[2]				Power				
			Intervention		Control		ERT vs. Placebo		PERT vs. Placebo		Combined HRT vs. Placebo
			Design	Revised[3]	Design	Revised[3]	Design[4]	Revised Adherence & Incidence Rates[5]	Design[4]	Revised Adherence & Incidence Rates[5]	
CHD	2001	17	2.71	2.01	3.26	2.41	46	32	54	41	63
		21	2.60	1.93	3.26	2.40	62	44	70	56	79
		24	2.49	1.84	3.25	2.39	76	57	84	70	91
	2004	17	4.16	3.50	5.03	4.15	64	47	73	59	82
		21	3.97	3.35	5.02	4.13	81	63	88	76	94
		24	3.79	3.20	5.01	4.11	92	77	96	88	99

[1] Analysis has not been updated from that of February 29, 2000.
[2] Intervention Effects and Percentage of Cases are shown for original Design assumptions. The other adherence patterns would produce greater incidence rates in Intervention women and a corresponding reduction in the estimated treatment effect.
[3] Revised incidence rates reflect greater healthy volunteer effects (67%, 50%, 37%) in years 1-3.
[4] Combined Drop-out and loss to follow-up rates of 7.9% in year 1, 4.9% per year thereafter; Drop-in rate of 1.5% per year.
[5] Combined Drop-out and loss to follow-up rates of 9.8% in year 1, 8.4% in year 2, and 6.9% per year thereafter; Drop-in rate of 2.5% per year. Average follow-up is 8.5 years.

Table 2.21
Baseline Characteristics of HRT Participants Enrolled in WHIMS

Data as of: August 31, 2001

	HRT Participants			
	Without Uterus		With Uterus	
Total HRT Participants	10739		16608	
Eligible HRT Population	4943		7302	
Enrolled in WHIMS	2970		4556	
% Enrolled of Total HRT		28%		27%
% Enrolled of Eligible		60%		62%
WHIMS Participants	**(N = 2970)**		**(N = 4556)**	
Age at Screening				
< 70	1423	(47.9%)	2293	(50.3%)
70-74	1062	(35.8%)	1540	(33.8%)
75+	485	(16.3%)	723	(15.9%)
Education				
Missing	10	(0.3%)	21	(0.5%)
0-8 years	67	(2.3%)	68	(1.5%)
Some high school	213	(7.2%)	231	(5.1%)
High school diploma/GED	705	(23.7%)	945	(20.7%)
School after high school	1246	(42.0%)	1773	(38.9%)
College degree or higher	729	(24.5%)	1518	(33.3%)
Ethnicity				
White	2457	(82.7%)	4064	(89.2%)
Black	326	(11.0%)	216	(4.7%)
Hispanic	84	(2.8%)	105	(2.3%)
American Indian	16	(0.5%)	10	(0.2%)
Asian/Pacific Islander	37	(1.2%)	91	(2.0%)
Other/Unspecified	50	(1.7%)	70	(1.5%)
Family Income				
Missing	182	(6.1%)	275	(6.0%)
< $10,000	226	(7.6%)	197	(4.3%)
$10,000 - $19,999	649	(21.9%)	789	(17.3%)
$20,000 - $34,999	897	(30.2%)	1325	(29.1%)
$35,000 - $49,999	516	(17.4%)	930	(20.4%)
$50,000 - $74,999	324	(10.9%)	660	(14.5%)
$75,000 +	176	(5.9%)	380	(8.3%)

Table 2.22
Cognitive Function Screening Scores for HRT Participants Enrolled in WHIMS

Data as of: August 31, 2001

	HRT Participants			
	Without Uterus		With Uterus	
	N	F39 Score	N	F39 Score
Baseline				
WHIMS	2939		4514	
25th Percentile		92		94
Median		96		97
Non-WHIMS	633		888	
25th Percentile		90		92
Median		95		96
Annual Visit 1				
WHIMS	2794		4311	
25th Percentile		94		95
Median		97		97
Non-WHIMS	1055		1606	
25th Percentile		92		93
Median		95		96
Annual Visit 2				
WHIMS	2613		4110	
25th Percentile		94		95
Median		97		97.5
Annual Visit 3				
WHIMS	2554		4024	
25th Percentile		94		95
Median		97		98
Non-WHIMS	1668		2444	
25th Percentile		92		93
Median		96		96
Annual Visit 4				
WHIMS	1346		2090	
25th Percentile		95		96
Median		97		98
Annual Visit 5				
WHIMS	113		161	
25th Percentile		93		96
Median		97		98

Table 2.23
Incidence of Probable Dementia in HRT Participants Enrolled in WHIMS

Data as of: August 31, 2001

	Without Uterus	With Uterus	All
Baseline			
F39 Completed	2939	4514	7453
Positive Screen	17	10	27
Diagnosis[1]	0	0	0
PD	2	1	3
MCI	5	3	8
ND	10	6	16
Unknown	0	0	0
AV1			
F39 Completed	2794	4311	7105
Positive Screen	79	87	166
Diagnosis[1]	0	0	0
PD	7	10	17
MCI	20	23	43
ND	39	44	83
Unknown	13	10	23
Deceased	0	1	1
AV2			
F39 Completed	2613	4110	6723
Positive Screen	116	123	239
Diagnosis[1]	0	0	0
PD	8	14	22
MCI	33	41	74
ND	50	53	103
Unknown	25	15	40
AV3			
F39 Completed	2554	4024	6578
Positive Screen	97	103	200
Diagnosis[1]	0	0	0
PD	9	8	17
MCI	20	31	51
ND	28	23	51
Unknown	40	41	81
Deceased	0	1	1
AV4			
F39 Completed	1346	2090	3436
Positive Screen	67	50	117
Diagnosis[1]	0	0	0
PD	13	12	25
MCI	8	4	12
ND	9	7	16
Unknown	37	27	64
AV5			
F39 Completed	113	161	274
Positive Screen	9	5	14
Diagnosis[1]	0	0	0
PD	3	1	4
MCI	1	0	1
ND	0	0	0
Unknown	5	4	9
Deceased	1	0	1

[1] Diagnoses: PD – Probable Dementia
MCI – Minor Cognitive Impairment
ND – No Dementia
Unknown – Refused phase 2/3 or materials are under review

3. DM Component

3.1 Recruitment

Age and race/ethnicity-specific DM recruitment data are presented in *Table 3.1*. The age-specific enrollment exceeded the design assumptions for ages 50-54, 55-59, and 60-69. For the age category 70-79, recruitment was lower than designed.

3.2 Adherence

Nutrient intake data for adherence monitoring are presented in *Table 3.2* and *Figure 3.1*. Studywide, the Food Frequency Questionnaire (FFQ) mean difference between Intervention and Control women is 10.9% energy from fat at AV-1 decreasing to 8.1% at AV-7. The C-I difference is slightly larger for women who were randomized later in WHI and were given reduced fat gram goals (*Table 3.3*). This report presents nutrient intake comparisons for each racial/ethnic group separately (*Table 3.4*). The C-I value in minority women is roughly 1-3 percentage points lower compared to white women. All C-I analyses are based on only those women providing a food frequency questionnaire at the designated visit. For example, missing data account for 11.5% of our sample at AV-1 and 15.2% at AV-3. The overall C-I percent energy from fat is approximately 2 to 3 percentage points lower than the design assumptions. Refer to *Sections 3.7* and *3.8* for a discussion of the impact of the C-I on study power and of the advanced adherence initiatives that are underway.

As shown in *Table 3.2* and *Figure 3.1*, for fruit and vegetable intake, the mean difference between the arms of the trial remains about 1.3 more servings per day for Intervention vs. Control women. Compared to Control women, Intervention women consumed almost 1 more serving per day of grains at AV-1, decreasing to one-half serving at AV-7. *Table 3.3* reports adherence among the 81% of women recruited after the fat gram goals were revised. *Table 3.4* presents adherence by race/ethnicity. Because of very sparse numbers, some of these results are highly variable.

Multivariate analyses were conducted to identify factors associated with C-I differences in percent energy from fat based on FFQs collected in the past year and controlling for visit year and clinic effect (*Table 3.5*). The only participant characteristics that are consistently associated with a lower C-I difference was being older than age 60-69 ($p<0.05$) or being Black compared to White ($p<0.05$). DM Participants randomized to HRT were also significantly more adherent than non-HRT participants. Separate analyses were conducted to examine session attendance, completion, and fat score provision variables in relation to C-I because these measures are highly correlated. For example, self-monitoring scores are almost always provided at sessions, and therefore session attendance (and completion) is closely associated with self-monitoring. Session attendance, completion, and self-monitoring are all significantly associated with much higher (i.e., better) C-I values.

Body weight data are presented in *Table 3.6*. The difference in body weight between Control and Intervention participants at AV-1 was almost 2 kg, decreasing to 0.4 kg at AV-7. Participants with revised fat gram goals have maintained a C-I difference of 0.9 kg at AV-6. From a trend perspective, these results are consistent with changes in energy intake estimated with the FFQ. The body weight data by race/ethnicity show that American Indians on the Intervention have maintained

the same mean weight for four years, while the control arm has gained 4-5 kg, producing marginally significant differences. Hispanic women in the Intervention group were heavier at baseline and this difference has continued. No trend in weight changes is seen for Black/African Americans.

Tables 3.7-3.8 give reasons for stopping DM categorized by general type and stratified by age and race/ethnicity. Overall, the major reasons for stopping given by participants were family responsibilities (13.5%), demands of work (11.6%), and issues of interest in the study (10.5%). Issues specifically related to the DM intervention were seldom mentioned. The age and race/ethnicity stratified analyses are new to this report, but have sparse numbers and may be confounded by other factors, and therefore should be interpreted cautiously. These data suggest that older participants were less likely to indicate that they were stopping due the demands of work, but were also less likely to stop the DM intervention because of issues related to interest in the study or because it was too far to the CC. Compared to the other groups, Hispanic/Latio women were most likely to indicate that they were stopping intervention because of family demands, but less likely to stop intervention because of interest in the study. Black/African American women were most likely to stop DM because of demands of work and whites women were most likely to indicate that they were stopping DM because it was too far to the CC.

3.3 Blood Specimen and Bone Density Analyses

Tables 3.9-3.10 present the results of blood specimen analyses from a small (4.3%) cohort of DM women selected randomly at baseline for these prospective analyses. This subsample incorporated oversampling of minorities. The results shown in *Table 3.9* are weighted to reflect the overall WHI distribution of race/ethnicity. *Table 3.10* presents analysis by race/ethnicity. Differences between baseline and AV-1 are mostly modest, with reductions of approximately 5% in LDL cholesterol and about 3% in total cholesterol for Intervention and Control women combined. There are no substantial changes in HDL-cholesterol or triglycerides in the combined groups. Blood specimen analyses are presented by race/ethnicity group and appear to be consistent with the dietary data. For example, LDL cholesterol reductions averaged 7% in Asian/Pacific Islander women and 5% in white women but are slightly lower among other groups (4% in Hispanic/Latinas and American Indian/Alaskan Native women and 3% in Blacks/African American). Note that baseline and AV-1 specimens were batched together for concurrent analyses by Medical Research Labs.

Tables 3.11-3.12 present blinded bone mineral density data from the DM bone density subsample overall and by race/ethnicity. Changes from baseline to AV-1 or AV-3 are interesting with increases in mean bone mineral density in the whole body scan as well as the spine and hip scan. An increase in BMD was not expected from this intervention. Possible reasons for this observation include use of calcium supplements and/or HRT, selection of health-conscious women, incomplete BMD data (12.6% missing at AV-3), or measurement issues.

3.4 Adherence to Follow-up

Table 3.13 summarizes adherence to follow-up contacts by treatment arm and contact type. Follow-up participation has been roughly equivalent in the two arms. The acceptable adherence rates specified by the Steering Committee for collection of outcome data are 90% at AV-1, with a decline

of no more than 1% per year, going no lower than 85%. WHI adherence rates are above those rates for all annual visits.

3.5 Vital Status

Table 3.14 presents data on the vital status and the participation status of participants in the DM trial. A detailed description of CCC and clinic activities to actively locate participants who do not complete their periodic visits is given in *Section 5 – Outcomes.* For operational purposes, we define CT participants to have an "unknown" participation status if there is no outcomes information from the participant for 18 months and no other contacts for 6 months. Currently, about 3.3% of the DM participants are lost-to-follow-up or have stopped follow-up (an increase of 0.1% compared to the Spring 2001 report), and 2.0% of the participants are known to be deceased. Virtually all of the remaining participants have completed a *Form 33 – Medical History Update* in the last 18 months. The design assumed that 3% per year would be lost-to-follow-up or death. Currently, the average follow-up for DM participants is about 4.7 years, suggesting that approximately 13.3% could be expected to be dead or lost-to-follow-up. Our overall rates compare favorably to design assumptions.

3.6 Outcomes

Table 3.15 contains counts of the number of locally verified major WHI outcomes for DM participants by race/ethnicity and age. Approximately 5% of the self-reported outcomes have not yet been verified, so the numbers in this table can be seen as a lower bound to the actual number of outcomes that have occurred. Compared to the design assumptions, we have observed almost 100% of the expected number of breast cancers, 75% of the expected number of colorectal cancers, about 60% of the expected number of CHD events, and about 30% of the expected number hip fractures.

Table 3.16 contains counts of the number of self-reports for some outcomes that are not locally verified in WHI. As most of the locally verified outcomes are somewhat over reported (see *Section 6.3 – Outcomes Data Quality)*, the number in this table should be taken as an upper bound to the number of events that have occurred in DM participants.

3.7 Power Considerations

The power under the design assumptions and under revised assumptions based on observed adherence and overall incidence rates through February 28, 2001 are shown in *Table 3.17.* While the observed Comparison - Intervention (C-I) differences represent a substantial achievement, they fall short of the assumptions of 13% C-I at AV-1 and subsequent decline of 0.25% per year. The lower than anticipated value of C-I at AV-1 will reduce the overall power of the study, but the size of the impact depends on the degree of adherence throughout the remaining years of follow-up. Under design assumptions, the study had 86% power for breast cancer and 90% for colorectal cancer. A second scenario assumes that the C-I starts at 11% but stays at 9% throughout the remaining follow-up. Using the final sample size and age distribution of DM participants, 8.5 years of average follow-up, and observed control rates for years 1-5 with adjustment toward design assumptions thereafter; the study is estimated to have 67% power for breast cancer and 60% power for colorectal cancer. We note that the intervention effect modeling for design considerations was based on percent of energy from fat. Other changes associated with the low fat eating pattern (e.g.,

in fruits, vegetables, and grains) would likely improve the power as these changes may have additional, complementary prevention effects.

3.8 Issues

As noted above, the C-I difference is less than the design assumptions. The WHI investigators and staff have undertaken a number of activities addressing adherence. In summer 1999, the DM Intervention incorporated an Intensive Intervention Program (IIP) that consisted of interviews using motivational enhancement techniques. Nutritionists targeted "medium adherers," defined as women who are attending some sessions but not meeting their fat gram goal or not self-monitoring (about 40% of intervention women). This protocol was completed on March 30, 2001. A preliminary evaluation of the IIP among intervention participants indicated that these contacts had a positive effect on fat intake among medium adherers. Specifically, when examining change (increases) in fat intake from AV-1 to most recent data collection, participants who received IIP contact had an increase in fat intake that was 0.75 percentage points less (i.e., had less slippage) than intervention women who did not receive IIP ($p<0.05$).

Currently all intervention woman are participating in a Targeted Message Campaign (TMC). The campaign began with a 2000 Fall/Winter Kickoff Newsletter to raise awareness and excitement. Starting in January 2001, participants receive a mailing introducing five themes to help them rediscover their intrinsic motivation(s) for participating in WHI. This first mailing is followed by a motivational enhancement phone call that supports participants in the process of identifying their primary motivation. Finally, based on information collected on the call, a second targeted mailing allows a woman to select an action consistent with her readiness to enhance her intervention adherence. This campaign will be completed at the end of 2001.

A Dietary Modification Working Group is developing a new initiative called the Personalized Evaluation of Fat Intake (PEFI). This intervention will use tailored, food-based, feedback to facilitate dietary goal setting for participants. The dietary assessment will be performed using a specially designed tool that focuses on usual fat-intake over past 4 weeks. After scanning, computerized algorithms will provide printed, individualized feedback on estimated grams of fat consumed (by foods) and food-specific behavioral change suggestions. The dietary questionnaire will be administered during summer 2002 group sessions. The written feedback will be provided and reinforced in Fall 2002 group sessions. CCs will conduct individual follow-up of group non-attendees by phone and mail.

Table 3.1
Dietary Modification Component Age – and Race/Ethnicity – Specific Recruitment

Data as of: August 31, 2001

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	**48,836**			
50-54	6961	149%	14%	10
55-59	11042	118%	23%	20
60-69	22715	108%	47%	45
70-79	8118	70%	17%	25
Race/Ethnicity	**48,836**			
American Indian	202		<1%	
Asian	1105		2%	
Black	5262		11%	
Hispanic	1845		4%	
White	39763		81%	
Other/Unspecified	659		1%	

Table 3.2
Nutrient Intake Monitoring

Data as of: August 31, 2001

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	19542	38.8	5.0	29294	38.8	5.0	0.0	0.0	0.83
FFQ Year 1[3]	18094	25.2	7.5	26762	36.1	6.9	10.9	0.1	0.00
FFQ Year 2[4]	5919	26.3	7.6	8654	36.3	7.0	9.9	0.1	0.00
FFQ Year 3[5]	3208	27.6	7.9	4856	37.3	7.1	9.7	0.2	0.00
FFQ Year 4[6]	4244	28.3	8.1	6642	37.6	7.1	9.3	0.1	0.00
FFQ Year 5[7]	3245	28.6	8.3	4965	37.7	7.4	9.2	0.2	0.00
FFQ Year 6[8]	2014	29.2	8.0	3045	37.4	7.2	8.2	0.2	0.00
FFQ Year 7[9]	641	29.4	8.1	1000	37.5	6.8	8.1	0.4	0.00
4DFR Baseline	892	32.8	6.4	1351	33.0	6.8	0.2	0.3	0.54
4DFR Year 1	805	21.7	7.3	1171	32.9	6.8	11.3	0.3	0.00
24 Hr Recall, Post-baseline	226	23.0	9.2	262	32.1	7.6	9.2	0.8	0.00
24 Hr Recall, Year 1	221	22.4	7.8	268	32.6	7.7	10.2	0.7	0.00
24 Hr Recall, Year 2	214	23.8	9.7	244	32.5	8.0	8.7	0.8	0.00
24 Hr Recall, Year 3	179	25.1	9.1	217	33.4	8.5	8.2	0.9	0.00
24 Hr Recall, Year 3 Cohort	762	24.8	8.5	1138	33.1	7.6	8.3	0.4	0.00
24 Hr Recall, Year 4	129	25.2	8.9	149	33.1	9.0	7.9	1.1	0.00
24 Hr Recall, Year 5	42	27.5	9.5	87	33.4	8.0	5.9	1.6	0.00
24 Hr Recall, Year 6	28	28.9	12.4	26	35.2	8.1	6.3	2.9	0.03
24 Hr Recall, Year 6 Cohort	150	26.0	8.9	258	33.0	7.8	7.0	0.8	0.00
Total Energy (kcal)									
FFQ Baseline	19542	1789	713	29294	1789	707	0	6.6	0.93
FFQ Year 1	18094	1474	534	26762	1584	642	110	5.8	0.00
FFQ Year 2	5919	1480	535	8654	1576	625	96	10.0	0.00
FFQ Year 3	3208	1476	537	4856	1572	644	96	13.7	0.00
FFQ Year 4	4244	1445	529	6642	1568	639	123	11.8	0.00
FFQ Year 5	3245	1473	533	4965	1576	644	103	13.6	0.00
FFQ Year 6	2014	1450	543	3045	1535	627	85	17.1	0.00
FFQ Year 7	641	1489	528	1000	1574	647	85	30.5	0.11
4DFR Baseline	892	1707	454	1351	1713	459	6	19.7	0.79
4DFR Year 1	805	1423	356	1171	1627	447	204	18.9	0.00
24 Hr Recall, Post-baseline	226	1520	418	262	1653	516	133	43.0	0.00
24 Hr Recall, Year 1	221	1482	418	268	1636	477	154	41.0	0.00
24 Hr Recall, Year 2	214	1435	430	244	1604	523	168	45.1	0.00
24 Hr Recall, Year 3	179	1455	426	217	1603	511	148	47.9	0.00
24 Hr Recall, Year 3 Cohort	762	1432	391	1138	1593	492	161	21.3	0.00
24 Hr Recall, Year 4	129	1499	399	149	1509	468	11	52.6	0.86
24 Hr Recall, Year 5	42	1470	534	87	1626	512	155	97.6	0.08
24 Hr Recall, Year 6	28	1435	384	26	1557	430	122	110.8	0.25
24 Hr Recall, Year 6 Cohort	150	1435	381	258	1548	481	113	45.9	0.05

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 4952 (27%) Intervention women had <=20% energy from fat at year 1.
[4] 1267 (21%) Intervention women had <=20% energy from fat at year 2.
[5] 566 (18%) Intervention women had <=20% energy from fat at year 3.
[6] 687 (16%) Intervention women had <=20% energy from fat at year 4.
[7] 501 (15%) Intervention women had <=20% energy from fat at year 5.
[8] 226 (11%) Intervention women had <=20% energy from fat at year 6.
[9] 68 (11%) Intervention women had <=20% energy from fat at year 7.

Table 3.2 (continued)
Nutrient Intake Monitoring
Data as of: August 31, 2001

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Total Fat (g)									
FFQ Baseline	19542	77.9	35.3	29294	77.8	34.7	0.0	0.3	0.87
FFQ Year 1	18094	41.5	21.8	26762	64.5	31.8	23.0	0.3	0.00
FFQ Year 2	5919	43.5	22.3	8654	64.5	31.3	21.0	0.5	0.00
FFQ Year 3	3208	45.8	23.7	4856	66.1	32.5	20.3	0.7	0.00
FFQ Year 4	4244	45.8	23.5	6642	66.3	32.4	20.5	0.6	0.00
FFQ Year 5	3245	47.3	24.6	4965	67.0	33.2	19.8	0.7	0.00
FFQ Year 6	2014	47.2	23.4	3045	64.6	31.8	17.4	0.8	0.00
FFQ Year 7	641	49.3	26.7	1000	66.6	33.1	17.3	1.6	0.00
4DFR Baseline	892	63.0	23.6	1351	63.8	24.6	0.8	1.0	0.71
4DFR Year 1	805	34.1	14.5	1171	60.4	23.5	26.4	0.9	0.00
24 Hr Recall, Post-baseline	226	39.6	21.9	262	60.5	26.9	20.9	2.2	0.00
24 Hr Recall, Year 1	221	36.9	17.1	268	60.6	25.1	23.7	2.0	0.00
24 Hr Recall, Year 2	214	38.8	22.6	244	59.3	27.2	20.6	2.4	0.00
24 Hr Recall, Year 3	179	41.1	20.3	217	60.9	28.0	19.7	2.5	0.00
24 Hr Recall, Year 3 Cohort	762	39.9	18.8	1138	60.1	25.8	20.2	1.1	0.00
24 Hr Recall, Year 4	129	42.2	20.3	149	57.2	26.3	14.9	2.9	0.00
24 Hr Recall, Year 5	42	46.0	26.1	87	61.9	28.0	16.0	5.2	0.00
24 Hr Recall, Year 6	28	45.8	21.8	26	62.4	28.6	16.7	6.9	0.01
24 Hr Recall, Year 6 Cohort	150	41.6	19.2	258	58.3	25.7	16.7	2.4	0.00
Saturated Fat (g)									
FFQ Baseline	19542	27.4	13.4	29294	27.3	13.2	0.1	0.1	0.85
FFQ Year 1	18094	14.2	8.1	26762	22.5	11.9	8.4	0.1	0.00
FFQ Year 2	5919	14.8	8.2	8654	22.5	11.7	7.7	0.2	0.00
FFQ Year 3	3208	15.5	8.9	4856	23.0	12.2	7.5	0.3	0.00
FFQ Year 4	4244	15.6	8.7	6642	23.2	12.3	7.6	0.2	0.00
FFQ Year 5	3245	16.1	9.2	4965	23.5	12.7	7.4	0.3	0.00
FFQ Year 6	2014	16.0	8.5	3045	22.7	12.2	6.7	0.3	0.00
FFQ Year 7	641	17.0	10.0	1000	23.6	12.8	6.5	0.6	0.00
4DFR Baseline	892	20.6	8.9	1351	20.9	9.3	0.3	0.4	0.72
4DFR Year 1	805	10.6	5.2	1171	19.5	8.3	9.0	0.3	0.00
24 Hr Recall, Post-baseline	226	12.9	7.9	262	20.1	9.6	7.2	0.8	0.00
24 Hr Recall, Year 1	221	11.7	6.2	268	20.1	10.1	8.4	0.8	0.00
24 Hr Recall, Year 2	214	12.3	8.2	244	19.5	9.9	7.2	0.9	0.00
24 Hr Recall, Year 3	179	13.7	7.6	217	20.4	10.9	6.7	1.0	0.00
24 Hr Recall, Year 3 Cohort	762	12.4	6.8	1138	19.8	9.4	7.4	0.4	0.00
24 Hr Recall, Year 4	129	13.6	7.7	149	19.2	10.6	5.6	1.1	0.00
24 Hr Recall, Year 5	42	14.3	7.7	87	21.5	10.5	7.2	1.8	0.00
24 Hr Recall, Year 6	28	14.8	6.2	26	22.3	12.9	7.6	2.7	0.00
24 Hr Recall, Year 6 Cohort	150	13.3	6.6	258	19.8	10.0	6.5	0.9	0.00

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.

Table 3.2 (continued)
Nutrient Intake Monitoring

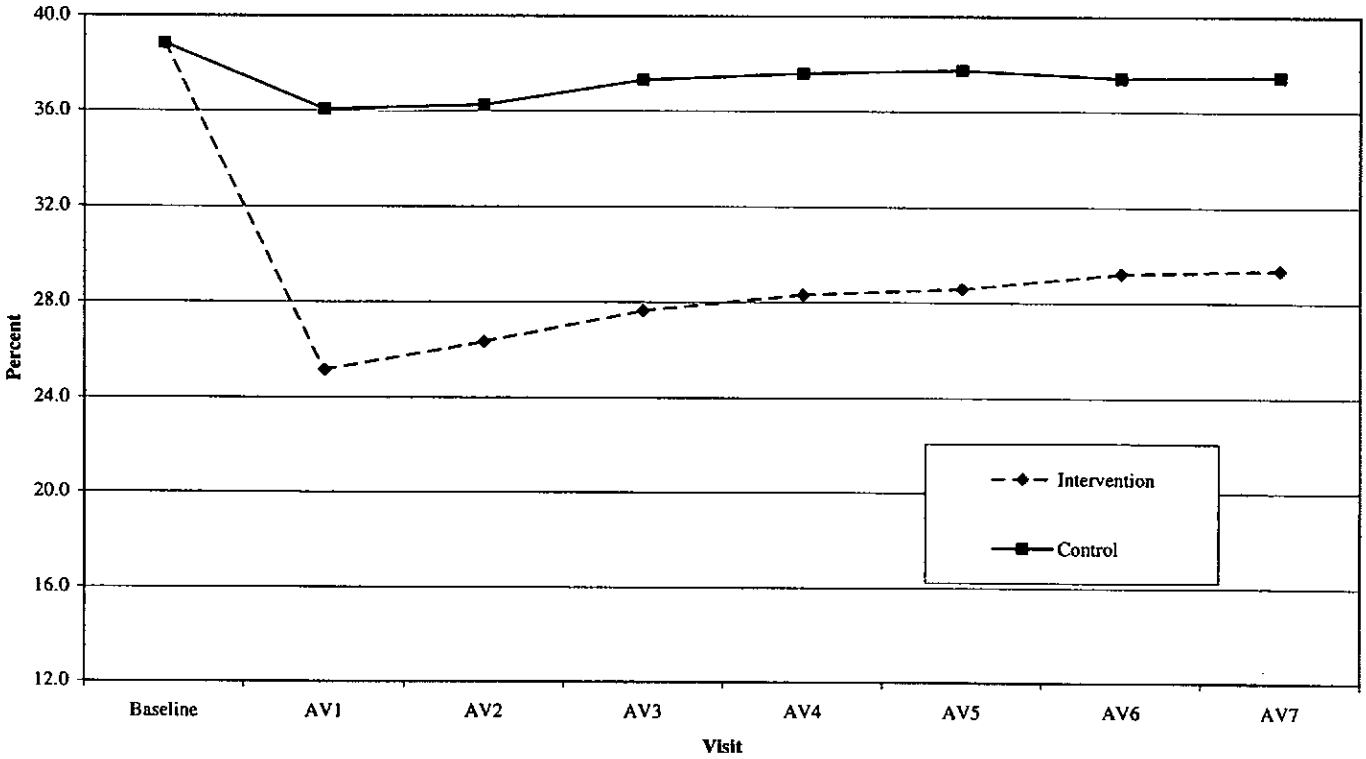
Data as of: August 31, 2001

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Polyunsaturated Fat (g)									
FFQ Baseline	19542	15.3	7.7	29294	15.3	7.6	0.0	0.1	0.78
FFQ Year 1	18094	7.9	4.4	26762	12.5	6.7	4.6	0.1	0.00
FFQ Year 2	5919	8.3	4.5	8654	12.4	6.5	4.1	0.1	0.00
FFQ Year 3	3208	8.8	4.7	4856	12.8	6.8	4.0	0.1	0.00
FFQ Year 4	4244	8.9	4.8	6642	12.8	6.7	3.9	0.1	0.00
FFQ Year 5	3245	9.1	5.1	4965	13.0	6.9	3.8	0.1	0.00
FFQ Year 6	2014	9.3	5.0	3045	12.4	6.4	3.2	0.2	0.00
FFQ Year 7	641	9.4	5.5	1000	12.7	6.7	3.3	0.3	0.00
4DFR Baseline	892	13.1	5.8	1351	13.5	6.1	0.3	0.3	0.40
4DFR Year 1	805	7.4	3.4	1171	12.7	6.2	5.3	0.2	0.00
24 Hr Recall, Post-baseline	226	8.3	5.0	262	12.6	7.3	4.3	0.6	0.00
24 Hr Recall, Year 1	221	7.8	4.4	268	12.4	6.3	4.7	0.5	0.00
24 Hr Recall, Year 2	214	8.3	5.7	244	12.5	7.6	4.2	0.6	0.00
24 Hr Recall, Year 3	179	8.4	5.0	217	12.4	6.5	4.1	0.6	0.00
24 Hr Recall, Year 3 Cohort	762	8.7	4.6	1138	12.3	6.9	3.6	0.3	0.00
24 Hr Recall, Year 4	129	8.9	4.9	149	11.6	7.2	2.6	0.7	0.00
24 Hr Recall, Year 5	42	9.7	7.5	87	12.1	9.0	2.4	1.6	0.04
24 Hr Recall, Year 6	28	9.2	6.1	26	12.0	6.4	2.8	1.7	0.02
24 Hr Recall, Year 6 Cohort	150	8.9	4.8	258	11.7	6.0	2.8	0.6	0.00
Fruits and Vegetables (servings)									
FFQ Baseline	19471	3.6	1.8	29216	3.6	1.8	0.0	0.0	0.69
FFQ Year 1	18013	5.1	2.3	26680	3.9	2.0	1.2	0.0	0.00
FFQ Year 2	5896	5.1	2.4	8622	3.9	2.0	1.2	0.0	0.00
FFQ Year 3	3202	5.2	2.5	4843	3.9	2.0	1.3	0.1	0.00
FFQ Year 4	4234	5.2	2.5	6630	3.8	2.0	1.3	0.0	0.00
FFQ Year 5	3223	5.2	2.5	4942	3.9	2.1	1.3	0.1	0.00
FFQ Year 6	1998	5.1	2.5	3029	3.8	2.0	1.3	0.1	0.00
FFQ Year 7	634	5.1	2.4	998	3.9	2.0	1.3	0.1	0.00
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	19469	4.7	2.5	29214	4.8	2.5	0.0	0.0	0.42
FFQ Year 1	18009	5.1	2.7	26670	4.2	2.3	0.8	0.0	0.00
FFQ Year 2	5895	4.9	2.5	8616	4.1	2.2	0.8	0.0	0.00
FFQ Year 3	3201	4.6	2.5	4838	4.0	2.2	0.7	0.1	0.00
FFQ Year 4	4231	4.4	2.4	6618	3.9	2.2	0.5	0.0	0.00
FFQ Year 5	3221	4.4	2.3	4937	3.9	2.2	0.5	0.1	0.00
FFQ Year 6	1998	4.4	2.5	3027	3.8	2.1	0.6	0.1	0.00
FFQ Year 7	634	4.4	2.2	998	3.9	2.1	0.5	0.1	0.00

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.

Figure 3.1
Nutrient Intake: % Energy from Fat[1]

Data as of: August 31, 2001

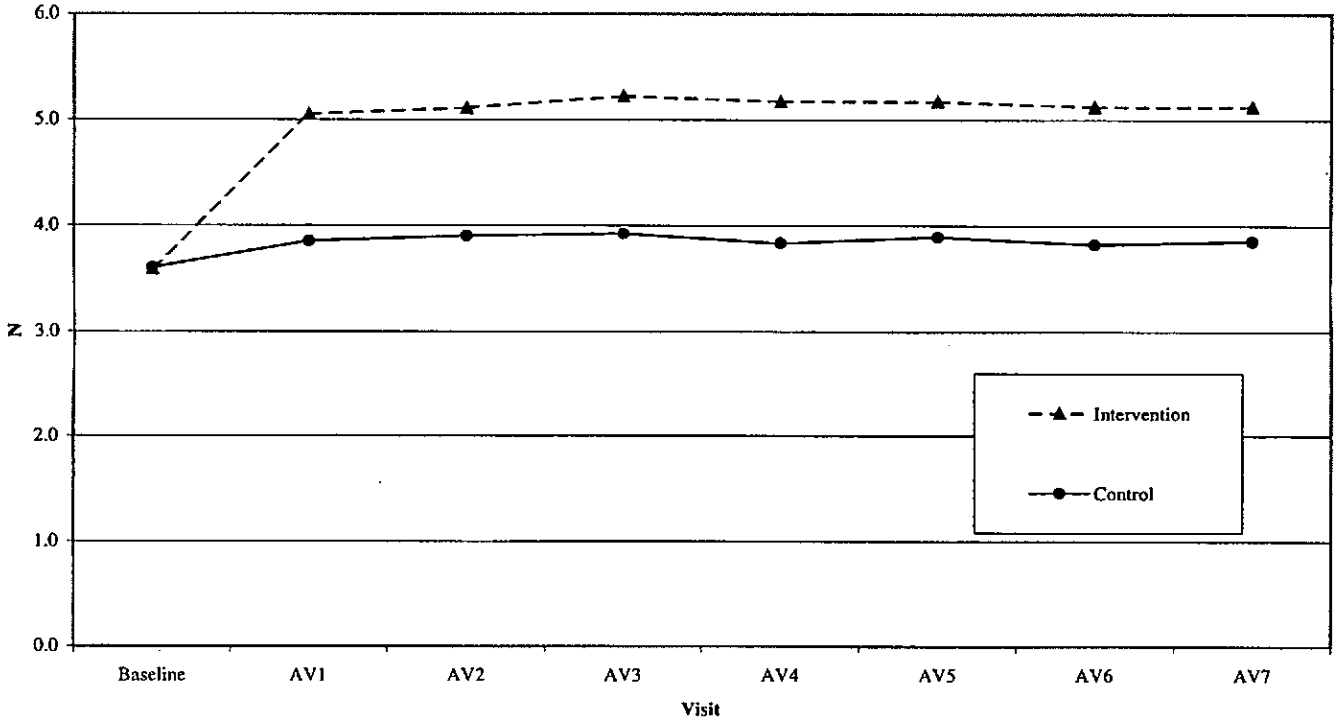


[1] Baseline % energy from fat values are about 3% higher in both groups due to the use of FFQ % energy from fat as an exclusionary criterion during screening.

Figure 3.1 (continued)
Nutrient Intake

Data as of: August 31, 2001

Fruit & Vegetable Servings per Day



Grain Servings per Day

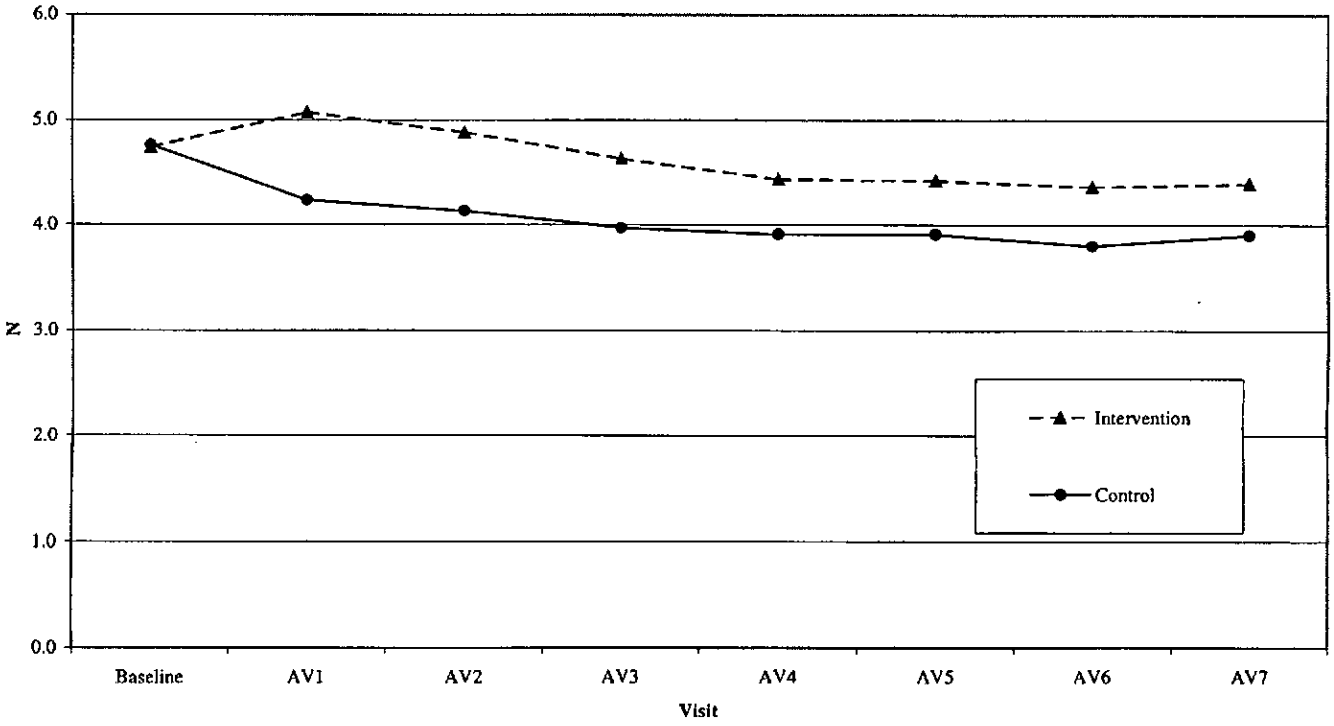


Table 3.3
Nutrient Intake Monitoring For Women With Revised Fat Gram Goals[1]

Data as of: August 31, 2001

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[2]	SE	p-value[3]
% Energy from Fat									
FFQ Baseline	15862	38.8	5.0	23753	38.8	5.0	0.0	0.1	0.47
FFQ Year 1	14667	25.3	7.6	21754	36.2	6.9	10.9	0.1	0.00
FFQ Year 2	4862	26.5	7.7	6992	36.6	7.0	10.1	0.1	0.00
FFQ Year 3	2790	27.9	8.0	4312	37.5	7.1	9.7	0.2	0.00
FFQ Year 4	3914	28.3	8.2	6156	37.7	7.1	9.4	0.2	0.00
FFQ Year 5	2787	28.6	8.4	4280	37.8	7.4	9.2	0.2	0.00
FFQ Year 6	374	29.1	8.3	455	37.7	7.4	8.5	0.5	0.00
4DFR Baseline	691	32.4	6.5	1038	33.0	6.9	0.6	0.3	0.06
4DFR Year 1	622	21.6	7.5	892	33.1	6.9	11.5	0.4	0.00
24 Hr Recall, Post-baseline	186	23.4	9.4	205	32.1	7.7	8.7	0.9	0.00
24 Hr Recall, Year 1	172	22.1	7.8	200	32.7	7.6	10.6	0.8	0.00
24 Hr Recall, Year 2	177	23.6	9.4	183	32.5	8.0	8.9	0.9	0.00
24 Hr Recall, Year 3	130	24.7	9.2	155	32.7	8.6	8.0	1.1	0.00
24 Hr Recall, Year 3 Cohort	593	24.8	8.5	883	33.3	7.8	8.5	0.4	0.00
24 Hr Recall, Year 4	87	24.6	9.2	89	33.7	9.9	9.2	1.4	0.00
24 Hr Recall, Year 5	12	31.0	10.0	26	35.0	7.9	4.1	3.0	0.23
Total Energy (kcal)									
FFQ Baseline	15862	1780	701	23753	1786	706	7	7.2	0.47
FFQ Year 1	14667	1468	533	21754	1588	644	120	6.4	0.00
FFQ Year 2	4862	1470	537	6992	1578	628	107	11.1	0.00
FFQ Year 3	2790	1471	533	4312	1575	646	104	14.7	0.00
FFQ Year 4	3914	1439	529	6156	1569	642	130	12.3	0.00
FFQ Year 5	2787	1471	538	4280	1577	650	106	14.8	0.00
FFQ Year 6	374	1440	584	455	1504	580	64	40.6	0.10
4DFR Baseline	691	1688	455	1038	1713	469	25	22.7	0.30
4DFR Year 1	622	1405	362	892	1621	447	216	21.6	0.00
24 Hr Recall, Post-baseline	186	1499	418	205	1640	524	141	48.3	0.00
24 Hr Recall, Year 1	172	1477	424	200	1654	489	177	47.9	0.00
24 Hr Recall, Year 2	177	1425	427	183	1583	499	158	49.0	0.01
24 Hr Recall, Year 3	130	1456	444	155	1553	510	97	57.2	0.10
24 Hr Recall, Year 3 Cohort	593	1421	388	883	1574	493	154	24.1	0.00
24 Hr Recall, Year 4	87	1484	400	89	1481	467	3	65.6	0.73
24 Hr Recall, Year 5	12	1548	800	26	1750	537	202	219.	0.22

(continues)

[1] Defined as women randomized after 6/15/95.
[2] Absolute difference.
[3] P-values based on testing in the natural log scale except for % Energy from fat.

Table 3.3 (continued)
Nutrient Intake Monitoring For Women With Revised Fat Gram Goals[1]

Data as of: August 31, 2001

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[2]	SE	p-value[3]
Total Fat (g)									
FFQ Baseline	15862	77.4	34.6	23753	77.6	34.6	0.1	0.4	0.63
FFQ Year 1	14667	41.7	22.0	21754	64.9	32.0	23.2	0.3	0.00
FFQ Year 2	4862	43.5	22.8	6992	65.0	31.5	21.5	0.5	0.00
FFQ Year 3	2790	46.0	23.7	4312	66.5	32.7	20.6	0.7	0.00
FFQ Year 4	3914	45.6	23.5	6156	66.6	32.6	21.0	0.6	0.00
FFQ Year 5	2787	47.3	24.9	4280	67.2	33.4	19.9	0.7	0.00
FFQ Year 6	374	47.1	25.7	455	64.0	30.6	16.9	2.0	0.00
4DFR Baseline	691	61.6	23.4	1038	63.8	25.1	2.2	1.2	0.12
4DFR Year 1	622	33.6	14.9	892	60.5	23.9	27.0	1.1	0.00
24 Hr Recall, Post-baseline	186	39.7	22.1	205	60.2	27.7	20.5	2.5	0.00
24 Hr Recall, Year 1	172	36.1	16.3	200	61.5	25.4	25.4	2.3	0.00
24 Hr Recall, Year 2	177	38.2	22.2	183	58.4	26.0	20.2	2.6	0.00
24 Hr Recall, Year 3	130	40.7	21.1	155	57.6	27.0	16.9	2.9	0.00
24 Hr Recall, Year 3 Cohort	593	39.6	18.7	883	59.9	26.1	20.3	1.2	0.00
24 Hr Recall, Year 4	87	41.2	21.6	89	57.1	27.2	15.9	3.7	0.00
24 Hr Recall, Year 5	12	56.0	38.1	26	70.5	35.1	14.6	12.6	0.14
Saturated Fat (g)									
FFQ Baseline	15862	27.2	13.2	23753	27.2	13.1	0.0	0.1	0.81
FFQ Year 1	14667	14.2	8.1	21754	22.6	11.9	8.5	0.1	0.00
FFQ Year 2	4862	14.8	8.4	6992	22.7	11.8	7.9	0.2	0.00
FFQ Year 3	2790	15.6	9.0	4312	23.1	12.3	7.5	0.3	0.00
FFQ Year 4	3914	15.5	8.7	6156	23.3	12.4	7.8	0.2	0.00
FFQ Year 5	2787	16.1	9.3	4280	23.6	12.8	7.5	0.3	0.00
FFQ Year 6	374	15.8	9.4	455	22.4	12.0	6.5	0.8	0.00
4DFR Baseline	691	20.0	8.8	1038	20.8	9.5	0.8	0.5	0.16
4DFR Year 1	622	10.3	5.3	892	19.3	8.3	9.0	0.4	0.00
24 Hr Recall, Post-baseline	186	13.0	8.0	205	20.0	9.7	7.0	0.9	0.00
24 Hr Recall, Year 1	172	11.3	5.9	200	20.4	10.2	9.1	0.9	0.00
24 Hr Recall, Year 2	177	12.0	8.2	183	19.0	9.2	7.0	0.9	0.00
24 Hr Recall, Year 3	130	13.5	7.9	155	19.2	10.9	5.7	1.1	0.00
24 Hr Recall, Year 3 Cohort	593	12.2	6.8	883	19.7	9.4	7.5	0.5	0.00
24 Hr Recall, Year 4	87	13.1	8.3	89	18.9	10.4	5.9	1.4	0.00
24 Hr Recall, Year 5	12	16.9	9.7	26	24.0	11.4	7.1	3.8	0.06

(continues)

[1] Defined as women randomized after 6/15/95.
[2] Absolute difference.
[3] P-values based on testing in the natural log scale except for % Energy from fat.

Table 3.3 (continued)
Nutrient Intake Monitoring For Women With Revised Fat Gram Goals[1]

Data as of: August 31, 2001

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[2]	SE	p-value[3]
Polyunsaturated Fat (g)									
FFQ Baseline	15862	15.1	7.4	23753	15.1	7.4	0.0	0.1	0.56
FFQ Year 1	14667	7.9	4.4	21754	12.5	6.7	4.6	0.1	0.00
FFQ Year 2	4862	8.3	4.6	6992	12.5	6.6	4.2	0.1	0.00
FFQ Year 3	2790	8.9	4.7	4312	12.9	6.8	4.1	0.1	0.00
FFQ Year 4	3914	8.9	4.8	6156	12.9	6.7	4.0	0.1	0.00
FFQ Year 5	2787	9.2	5.2	4280	13.0	7.0	3.8	0.2	0.00
FFQ Year 6	374	9.2	5.3	455	12.5	6.2	3.3	0.4	0.00
4DFR Baseline	691	12.8	5.7	1038	13.5	6.3	0.7	0.3	0.06
4DFR Year 1	622	7.4	3.5	892	12.9	6.5	5.5	0.3	0.00
24 Hr Recall, Post-baseline	186	8.3	5.1	205	12.4	7.4	4.1	0.6	0.00
24 Hr Recall, Year 1	172	7.6	4.3	200	12.6	6.2	4.9	0.6	0.00
24 Hr Recall, Year 2	177	8.3	5.4	183	12.2	7.3	4.0	0.7	0.00
24 Hr Recall, Year 3	130	8.2	5.1	155	11.7	6.1	3.5	0.7	0.00
24 Hr Recall, Year 3 Cohort	593	8.7	4.5	883	12.2	6.9	3.5	0.3	0.00
24 Hr Recall, Year 4	87	8.9	5.2	89	12.1	8.1	3.2	1.0	0.00
24 Hr Recall, Year 5	12	11.6	12.1	26	15.4	14.2	3.8	4.7	0.19
Fruits and Vegetables (servings)									
FFQ Baseline	15821	3.6	1.8	23707	3.6	1.9	0.0	0.0	0.64
FFQ Year 1	14618	5.0	2.4	21698	3.9	2.0	1.2	0.0	0.00
FFQ Year 2	4847	5.1	2.4	6974	3.9	2.0	1.2	0.0	0.00
FFQ Year 3	2787	5.2	2.5	4307	3.9	2.0	1.3	0.1	0.00
FFQ Year 4	3907	5.2	2.5	6151	3.8	2.0	1.4	0.0	0.00
FFQ Year 5	2767	5.2	2.5	4262	3.9	2.1	1.3	0.1	0.00
FFQ Year 6	373	5.1	2.7	453	3.8	2.0	1.3	0.2	0.00
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	15819	4.7	2.5	23705	4.8	2.5	0.0	0.0	0.20
FFQ Year 1	14614	5.0	2.6	21689	4.2	2.3	0.8	0.0	0.00
FFQ Year 2	4846	4.8	2.5	6969	4.1	2.2	0.7	0.0	0.00
FFQ Year 3	2786	4.6	2.5	4302	4.0	2.2	0.6	0.1	0.00
FFQ Year 4	3904	4.4	2.4	6141	3.9	2.2	0.5	0.0	0.00
FFQ Year 5	2765	4.4	2.3	4259	3.9	2.2	0.5	0.1	0.00
FFQ Year 6	373	4.3	2.4	451	3.7	2.0	0.6	0.2	0.00

[1] Defined as women randomized after 6/15/95.
[2] Absolute difference.
[3] P-values based on testing in the natural log scale except for % Energy from fat.

Table 3.4
Nutrient Intake Monitoring in American Indian/Alaskan Native Women[1]

Data as of: August 31, 2001

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[2]	SE	p-value[3]
% Energy from Fat									
FFQ Baseline	88	39.5	5.7	114	40.0	5.2	0.5	0.8	0.49
FFQ Year 1[4]	73	27.5	8.9	96	38.0	8.0	10.5	1.3	0.00
FFQ Year 2[5]	28	26.9	8.8	32	38.2	6.8	11.3	2.0	0.00
FFQ Year 3[6]	18	31.3	8.9	40	38.3	6.8	7.0	2.1	0.01
FFQ Year 4[7]	23	30.3	9.3	28	39.9	7.6	9.6	2.4	0.00
FFQ Year 5[8]	15	28.3	8.1	13	38.2	6.8	9.9	2.8	0.00
FFQ Year 6[9]	6	34.5	7.7	11	37.6	6.6	3.1	3.5	0.43
4DFR Baseline	24	34.0	6.7	44	33.4	7.8	0.6	1.9	0.73
4DFR Year 1	18	20.5	6.2	32	34.6	7.4	14.2	2.1	0.00
Total Energy (kcal)									
FFQ Baseline	88	1717	796	114	1772	718	54	106.8	0.42
FFQ Year 1	73	1631	690	96	1546	753	86	112.8	0.52
FFQ Year 2	28	1508	566	32	1554	707	46	166.9	0.95
FFQ Year 3	18	1520	614	40	1609	701	89	191.8	0.75
FFQ Year 4	23	1441	479	28	1821	933	380	214.8	0.09
FFQ Year 5	15	1799	675	13	1354	759	445	270.9	0.05
FFQ Year 6	6	1048	247	11	1882	509	834	223.2	0.00
4DFR Baseline	24	1524	426	44	1672	607	148	139.7	0.47
4DFR Year 1	18	1284	419	32	1632	613	348	162.7	0.04
Total Fat (g)									
FFQ Baseline	88	76.5	40.3	114	79.3	35.6	2.8	5.4	0.34
FFQ Year 1	73	50.3	29.6	96	67.1	43.6	16.8	5.9	0.00
FFQ Year 2	28	45.8	29.0	32	68.5	40.0	22.7	9.1	0.01
FFQ Year 3	18	56.6	35.4	40	69.7	35.4	13.1	10.0	0.17
FFQ Year 4	23	48.9	21.7	28	81.3	44.5	32.4	10.2	0.00
FFQ Year 5	15	56.9	27.4	13	60.2	42.5	3.3	13.3	0.98
FFQ Year 6	6	39.9	13.6	11	79.3	27.2	39.4	12.0	0.00
4DFR Baseline	24	57.4	17.5	44	63.8	30.8	6.4	6.8	0.83
4DFR Year 1	18	29.4	12.9	32	64.9	33.0	35.5	8.1	0.00

[1] Insufficient sample size for FFQ Year 7.
[2] Absolute difference.
[3] P-values based on testing in the natural log scale except for % Energy from fat.
[4] 14 (19%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 1.
[5] 6 (21%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 2.
[6] 1 (6%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 3.
[7] 5 (22%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 4.
[8] 2 (13%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 5.
[9] 1 (17%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 6.

Table 3.4 (continued)
Nutrient Intake Monitoring in American Indian/Alaskan Native Women[1]

Data as of: August 31, 2001

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[2]	SE	p-value[3]
Saturated Fat (g)									
FFQ Baseline	88	26.9	14.2	114	27.9	14.1	1.0	2.0	0.42
FFQ Year 1[4]	73	17.4	11.0	96	23.7	18.0	6.2	2.4	0.00
FFQ Year 2[5]	28	15.5	9.9	32	23.3	14.9	7.8	3.3	0.01
FFQ Year 3[6]	18	19.8	13.9	40	23.3	11.8	3.4	3.5	0.22
FFQ Year 4[7]	23	17.2	8.4	28	28.3	16.6	11.2	3.8	0.00
FFQ Year 5[8]	15	20.2	12.2	13	22.0	18.2	1.8	5.8	0.92
FFQ Year 6[9]	6	13.0	5.6	11	27.9	13.0	15.0	5.6	0.01
4DFR Baseline	24	19.1	6.9	44	21.5	12.3	2.4	2.7	0.87
4DFR Year 1	18	9.0	4.2	32	21.0	10.9	12.0	2.7	0.00
Polyunsaturated Fat (g)									
FFQ Baseline	88	15.2	9.5	114	15.3	7.6	0.1	1.2	0.48
FFQ Year 1	73	9.4	6.3	96	12.7	8.5	3.3	1.2	0.00
FFQ Year 2	28	8.9	6.6	32	14.0	8.8	5.1	2.0	0.01
FFQ Year 3	18	10.2	5.8	40	14.2	7.9	4.0	2.1	0.08
FFQ Year 4	23	9.3	4.7	28	15.6	8.9	6.3	2.1	0.00
FFQ Year 5	15	10.5	3.8	13	10.1	5.5	0.4	1.8	0.58
FFQ Year 6	6	7.9	3.0	11	15.3	5.5	7.4	2.5	0.01
4DFR Baseline	24	11.5	4.6	44	12.2	6.2	0.7	1.5	0.92
4DFR Year 1	18	6.9	3.8	32	13.6	9.6	6.7	2.4	0.00
Fruits and Vegetables (servings)									
FFQ Baseline	88	3.5	2.0	114	3.0	1.6	0.4	0.2	0.23
FFQ Year 1	73	5.1	2.9	96	3.6	2.1	1.6	0.4	0.00
FFQ Year 2	28	5.2	3.3	32	3.3	1.6	1.9	0.7	0.05
FFQ Year 3	18	4.9	2.0	40	3.8	2.4	1.0	0.6	0.03
FFQ Year 4	23	5.1	3.1	28	4.0	2.1	1.1	0.7	0.25
FFQ Year 5	15	5.9	2.6	13	3.0	1.4	2.9	0.8	0.00
FFQ Year 6	6	3.6	2.6	11	4.0	2.2	0.4	1.2	0.58
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	88	4.5	2.5	114	4.7	2.7	0.2	0.4	0.49
FFQ Year 1	73	5.5	3.4	96	4.2	2.3	1.3	0.4	0.02
FFQ Year 2	28	5.5	3.0	32	4.3	2.9	1.3	0.8	0.15
FFQ Year 3	18	4.2	2.6	40	4.2	2.5	0.1	0.7	0.72
FFQ Year 4	23	4.2	2.2	28	4.5	2.8	0.3	0.7	0.72
FFQ Year 5	15	4.7	2.7	13	3.7	2.1	0.9	0.9	0.34
FFQ Year 6	6	3.1	1.7	11	6.0	1.9	3.0	0.9	0.01

[1] Insufficient sample size for FFQ Year 7.
[2] Absolute difference.
[3] P-values based on testing in the natural log scale except for % Energy from fat.
[4] 14 (19%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 1.
[5] 6 (21%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 2.
[6] 1 (6%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 3.
[7] 5 (22%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 4.
[8] 2 (13%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 5.
[9] 1 (17%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 6.

Table 3.4 (continued)
Nutrient Intake Monitoring in Asian/Pacific Islander Women

Data as of: August 31, 2001

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	431	37.7	4.4	674	38.4	4.7	0.7	0.3	0.02
FFQ Year 1[3]	408	25.8	7.3	628	36.1	6.6	10.3	0.4	0.00
FFQ Year 2[4]	147	27.2	7.4	213	36.1	6.9	8.9	0.8	0.00
FFQ Year 3[5]	106	28.0	7.6	151	36.3	6.4	8.3	0.9	0.00
FFQ Year 4[6]	96	29.2	8.4	173	37.3	6.7	8.1	0.9	0.00
FFQ Year 5[7]	80	27.3	7.8	107	36.8	7.4	9.4	1.1	0.00
FFQ Year 6[8]	15	27.3	6.6	28	39.4	5.0	12.1	1.8	0.00
FFQ Year 7[9]	5	27.4	9.8	6	36.5	6.0	9.1	4.8	0.12
4DFR Baseline	70	30.2	5.4	104	31.4	6.8	1.2	1.0	0.18
4DFR Year 1	68	21.5	7.6	88	31.6	5.8	10.1	1.1	0.00
Total Energy (kcal)									
FFQ Baseline	431	1700	723	674	1675	711	25	44.1	0.50
FFQ Year 1	408	1502	588	628	1524	636	22	39.2	0.94
FFQ Year 2	147	1512	637	213	1500	777	12	77.6	0.24
FFQ Year 3	106	1500	632	151	1418	584	82	76.6	0.28
FFQ Year 4	96	1488	619	173	1489	600	0	77.3	0.70
FFQ Year 5	80	1557	626	107	1425	538	132	85.3	0.13
FFQ Year 6	15	1614	565	28	1619	440	5	155.5	0.76
FFQ Year 7	5	1401	384	6	1171	148	230	168.8	0.28
4DFR Baseline	70	1683	400	104	1732	388	49	60.7	0.38
4DFR Year 1	68	1525	374	88	1620	397	95	62.5	0.12
Total Fat (g)									
FFQ Baseline	431	71.9	34.1	674	72.2	34.8	0.4	2.1	0.99
FFQ Year 1	408	43.5	23.5	628	62.4	31.4	18.9	1.8	0.00
FFQ Year 2	147	46.1	24.7	213	61.1	35.6	15.0	3.4	0.00
FFQ Year 3	106	47.3	28.2	151	57.8	28.0	10.5	3.6	0.00
FFQ Year 4	96	49.5	29.5	173	62.3	29.2	12.8	3.7	0.00
FFQ Year 5	80	48.8	29.2	107	58.3	24.3	9.4	3.9	0.00
FFQ Year 6	15	48.9	22.5	28	70.9	22.2	22.1	7.1	0.00
FFQ Year 7	5	44.1	25.6	6	47.3	8.2	3.2	11.0	0.51
4DFR Baseline	70	57.1	19.1	104	61.8	23.4	4.7	3.4	0.24
4DFR Year 1	68	36.6	17.4	88	57.6	19.9	21.0	3.0	0.00

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 99 (24%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 1.
[4] 24 (16%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 2.
[5] 18 (17%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 3.
[6] 12 (13%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 4.
[7] 13 (16%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 5.
[8] 1 (7%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 6.
[9] 2 (40%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 7.

Table 3.4 (continued)
Nutrient Intake Monitoring in Asian/Pacific Islander Women

Data as of: August 31, 2001

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	431	22.8	12.0	674	22.9	12.0	0.1	0.7	0.94
FFQ Year 1[3]	408	13.5	8.0	628	19.6	10.8	6.0	0.6	0.00
FFQ Year 2[4]	147	14.3	8.5	213	19.3	11.9	5.0	1.1	0.00
FFQ Year 3[5]	106	14.8	10.2	151	18.1	9.8	3.3	1.3	0.00
FFQ Year 4[6]	96	15.5	10.4	173	19.6	9.4	4.1	1.2	0.00
FFQ Year 5[7]	80	15.2	10.0	107	18.2	8.8	3.0	1.4	0.01
FFQ Year 6[8]	15	14.9	7.7	28	22.6	8.5	7.7	2.6	0.00
FFQ Year 7[9]	5	13.3	7.5	6	15.0	3.6	1.6	3.4	0.44
4DFR Baseline	70	17.2	7.1	104	18.8	8.4	1.7	1.2	0.26
4DFR Year 1	68	10.5	5.5	88	17.7	7.2	7.2	1.0	0.00
Polyunsaturated Fat (g)									
FFQ Baseline	431	15.6	7.4	674	15.7	7.8	0.0	0.5	0.54
FFQ Year 1	408	9.1	5.0	628	13.6	7.2	4.5	0.4	0.00
FFQ Year 2	147	9.9	5.5	213	13.1	8.0	3.2	0.8	0.00
FFQ Year 3	106	10.0	5.7	151	12.1	6.1	2.1	0.8	0.00
FFQ Year 4	96	10.7	6.3	173	13.2	6.5	2.5	0.8	0.00
FFQ Year 5	80	10.6	7.9	107	12.7	5.3	2.1	1.0	0.00
FFQ Year 6	15	10.4	5.0	28	15.0	4.4	4.6	1.5	0.01
FFQ Year 7	5	9.6	5.8	6	8.7	2.3	0.9	2.5	0.98
4DFR Baseline	70	13.1	5.3	104	14.6	6.5	1.5	0.9	0.12
4DFR Year 1	68	8.8	4.4	88	12.9	5.9	4.1	0.9	0.00
Fruits and Vegetables (servings)									
FFQ Baseline	429	3.4	1.7	674	3.3	1.9	0.1	0.1	0.26
FFQ Year 1	406	4.7	2.4	628	3.5	2.0	1.2	0.1	0.00
FFQ Year 2	146	4.8	2.7	213	3.4	1.9	1.4	0.2	0.00
FFQ Year 3	106	4.9	2.5	151	3.4	2.1	1.5	0.3	0.00
FFQ Year 4	95	4.7	2.3	173	3.3	1.9	1.4	0.3	0.00
FFQ Year 5	80	5.4	2.2	107	3.6	2.1	1.8	0.3	0.00
FFQ Year 6	15	5.8	2.9	28	3.8	1.8	2.1	0.7	0.10
FFQ Year 7	5	4.8	1.8	6	3.2	1.3	1.6	0.9	0.10
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	429	5.0	2.6	674	4.8	2.3	0.2	0.1	0.43
FFQ Year 1	406	5.8	2.7	628	4.5	2.2	1.3	0.2	0.00
FFQ Year 2	146	5.4	2.7	213	4.3	2.5	1.1	0.3	0.00
FFQ Year 3	106	5.1	2.4	151	4.2	2.2	0.9	0.3	0.01
FFQ Year 4	95	5.2	2.4	173	4.4	2.2	0.8	0.3	0.00
FFQ Year 5	80	5.3	2.4	107	4.2	2.0	1.2	0.3	0.00
FFQ Year 6	15	6.0	3.0	28	4.6	1.9	1.4	0.7	0.29
FFQ Year 7	5	6.2	3.0	6	3.4	1.2	2.8	1.3	0.04

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 99 (24%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 1.
[4] 24 (16%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 2.
[5] 18 (17%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 3.
[6] 12 (13%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 4.
[7] 13 (16%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 5.
[8] 1 (7%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 6.
[9] 2 (40%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 7.

Table 3.4 (continued)
Nutrient Intake Monitoring in Black/African American Women

Data as of: August 31, 2001

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	2135	39.7	5.3	3127	39.9	5.2	0.1	0.1	0.41
FFQ Year 1[3]	1858	28.0	8.4	2625	36.9	7.4	8.8	0.2	0.00
FFQ Year 2[4]	611	29.4	8.0	824	36.4	7.4	7.0	0.4	0.00
FFQ Year 3[5]	347	29.3	7.8	507	38.2	7.2	8.9	0.5	0.00
FFQ Year 4[6]	387	30.1	7.9	620	37.6	7.4	7.5	0.5	0.00
FFQ Year 5[7]	333	30.7	7.9	486	37.3	7.9	6.6	0.6	0.00
FFQ Year 6[8]	232	31.1	8.0	300	37.1	7.8	6.0	0.7	0.00
FFQ Year 7[9]	30	31.9	8.8	51	37.9	6.7	6.0	1.7	0.00
4DFR Baseline	243	34.0	6.7	371	34.2	6.9	0.2	0.6	0.76
4DFR Year 1	219	23.5	7.9	307	34.2	7.0	10.8	0.7	0.00
Total Energy (kcal)									
FFQ Baseline	2135	1744	827	3127	1739	835	5	23.3	0.72
FFQ Year 1	1858	1383	633	2625	1492	775	109	21.8	0.00
FFQ Year 2	611	1391	718	824	1450	725	58	38.5	0.32
FFQ Year 3	347	1390	632	507	1539	794	149	51.0	0.02
FFQ Year 4	387	1330	567	620	1443	740	113	44.0	0.05
FFQ Year 5	333	1353	593	486	1382	699	29	46.8	0.91
FFQ Year 6	232	1285	559	300	1378	720	93	57.3	0.33
FFQ Year 7	30	1409	535	51	1300	711	109	150.0	0.10
4DFR Baseline	243	1704	526	371	1651	478	53	41.1	0.32
4DFR Year 1	219	1346	342	307	1585	482	239	38.0	0.00
Total Fat (g)									
FFQ Baseline	2135	77.7	40.7	3127	77.9	41.3	0.1	1.2	0.92
FFQ Year 1	1858	43.6	26.8	2625	62.3	37.3	18.7	1.0	0.00
FFQ Year 2	611	46.4	32.5	824	60.1	36.0	13.7	1.8	0.00
FFQ Year 3	347	46.2	27.0	507	66.4	38.8	20.2	2.4	0.00
FFQ Year 4	387	44.7	23.9	620	61.2	35.9	16.5	2.1	0.00
FFQ Year 5	333	47.0	26.4	486	58.6	35.6	11.7	2.3	0.00
FFQ Year 6	232	45.0	25.1	300	57.8	34.7	12.8	2.7	0.00
FFQ Year 7	30	50.3	25.5	51	56.9	35.2	6.5	7.4	0.85
4DFR Baseline	243	65.1	25.7	371	64.0	26.3	1.2	2.2	0.54
4DFR Year 1	219	34.9	14.7	307	61.5	25.7	26.6	1.9	0.00

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 322 (17%) Black/African American Intervention women had <=20% energy from fat at year 1.
[4] 80 (13%) Black/African American Intervention women had <=20% energy from fat at year 2.
[5] 46 (13%) Black/African American Intervention women had <=20% energy from fat at year 3.
[6] 46 (12%) Black/African American Intervention women had <=20% energy from fat at year 4.
[7] 29 (9%) Black/African American Intervention women had <=20% energy from fat at year 5.
[8] 20 (9%) Black/African American Intervention women had <=20% energy from fat at year 6.
[9] 1 (3%) Black/African American Intervention women had <=20% energy from fat at year 7.

Table 3.4 (continued)
Nutrient Intake Monitoring in Black/African American Women

Data as of: August 31, 2001

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	2135	25.8	14.3	3127	25.9	14.7	0.1	0.4	0.91
FFQ Year 1[3]	1858	14.3	9.2	2625	20.5	12.8	6.2	0.3	0.00
FFQ Year 2[4]	611	15.3	11.8	824	19.8	12.3	4.5	0.6	0.00
FFQ Year 3[5]	347	15.0	9.5	507	21.8	13.4	6.8	0.8	0.00
FFQ Year 4[6]	387	14.3	8.2	620	20.1	12.5	5.8	0.7	0.00
FFQ Year 5[7]	333	15.1	9.0	486	19.2	12.6	4.1	0.8	0.00
FFQ Year 6[8]	232	14.5	8.3	300	19.1	12.6	4.6	1.0	0.00
FFQ Year 7[9]	30	16.8	10.9	51	19.3	13.3	2.5	2.9	0.75
4DFR Baseline	243	20.3	9.3	371	20.2	9.1	0.1	0.8	0.96
4DFR Year 1	219	10.6	5.2	307	18.7	8.2	8.1	0.6	0.00
Polyunsaturated Fat (g)									
FFQ Baseline	2135	16.0	8.9	3127	16.0	8.9	0.0	0.3	0.98
FFQ Year 1	1858	8.7	5.6	2625	12.7	8.0	4.0	0.2	0.00
FFQ Year 2	611	9.2	6.2	824	12.1	7.5	3.0	0.4	0.00
FFQ Year 3	347	9.3	5.6	507	13.4	8.0	4.1	0.5	0.00
FFQ Year 4	387	9.2	5.1	620	12.5	7.6	3.3	0.4	0.00
FFQ Year 5	333	9.5	5.6	486	12.1	8.1	2.6	0.5	0.00
FFQ Year 6	232	9.2	5.8	300	11.7	7.2	2.5	0.6	0.00
FFQ Year 7	30	10.6	5.5	51	10.8	6.3	0.2	1.4	0.76
4DFR Baseline	243	14.5	6.7	371	13.8	6.8	0.7	0.6	0.15
4DFR Year 1	219	7.6	3.2	307	13.7	6.9	6.1	0.5	0.00
Fruits and Vegetables (servings)									
FFQ Baseline	2132	3.3	1.9	3123	3.2	1.9	0.0	0.1	0.73
FFQ Year 1	1852	4.5	2.6	2619	3.4	2.1	1.1	0.1	0.00
FFQ Year 2	610	4.5	2.6	819	3.5	2.2	1.0	0.1	0.00
FFQ Year 3	347	4.8	2.7	507	3.7	2.3	1.0	0.2	0.00
FFQ Year 4	387	4.9	2.8	620	3.5	2.2	1.5	0.2	0.00
FFQ Year 5	331	4.7	2.8	485	3.6	2.2	1.2	0.2	0.00
FFQ Year 6	232	4.5	2.5	298	3.5	2.2	1.0	0.2	0.00
FFQ Year 7	30	5.3	2.6	51	3.1	2.0	2.2	0.5	0.00
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	2132	4.5	2.8	3122	4.4	2.8	0.1	0.1	0.32
FFQ Year 1	1851	4.4	2.8	2617	3.8	2.5	0.6	0.1	0.00
FFQ Year 2	610	4.2	2.6	818	3.7	2.4	0.5	0.1	0.00
FFQ Year 3	347	4.2	2.7	507	3.8	2.5	0.4	0.2	0.01
FFQ Year 4	387	4.0	2.4	618	3.6	2.3	0.4	0.2	0.00
FFQ Year 5	331	3.9	2.3	484	3.5	2.2	0.4	0.2	0.00
FFQ Year 6	232	3.7	2.2	298	3.3	2.0	0.4	0.2	0.01
FFQ Year 7	30	3.6	1.6	51	3.4	2.3	0.2	0.5	0.24

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 322 (17%) Black/African American Intervention women had <=20% energy from fat at year 1.
[4] 80 (13%) Black/African American Intervention women had <=20% energy from fat at year 2.
[5] 46 (13%) Black/African American Intervention women had <=20% energy from fat at year 3.
[6] 46 (12%) Black/African American Intervention women had <=20% energy from fat at year 4.
[7] 29 (9%) Black/African American Intervention women had <=20% energy from fat at year 5.
[8] 20 (9%) Black/African American Intervention women had <=20% energy from fat at year 6.
[9] 1 (3%) Black/African American Intervention women had <=20% energy from fat at year 7.

Table 3.4 (continued)
Nutrient Intake Monitoring in Hispanic/Latino Women

Data as of: August 31, 2001

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	751	39.3	5.1	1094	39.0	5.1	0.4	0.2	0.13
FFQ Year 1[3]	617	27.9	8.0	914	36.1	7.4	8.2	0.4	0.00
FFQ Year 2[4]	226	27.7	8.3	303	36.9	7.6	9.2	0.7	0.00
FFQ Year 3[5]	129	29.9	8.9	193	37.3	7.3	7.4	0.9	0.00
FFQ Year 4[6]	138	30.8	8.0	246	36.8	7.3	6.0	0.8	0.00
FFQ Year 5[7]	100	28.6	8.9	162	36.8	7.3	8.3	1.0	0.00
FFQ Year 6[8]	48	28.4	8.5	73	36.4	6.2	8.0	1.3	0.00
FFQ Year 7[9]	10	30.5	11.3	21	37.3	4.8	6.8	2.9	0.09
4DFR Baseline	96	32.4	5.7	134	32.4	6.5	0.1	0.8	0.95
4DFR Year 1	82	23.1	7.4	110	32.0	7.3	8.9	1.1	0.00
Total Energy (kcal)									
FFQ Baseline	751	1847	836	1094	1859	871	13	40.6	0.86
FFQ Year 1	617	1419	665	914	1571	862	152	41.1	0.00
FFQ Year 2	226	1411	615	303	1620	768	209	62.1	0.00
FFQ Year 3	129	1533	642	193	1568	709	35	77.7	0.84
FFQ Year 4	138	1404	663	246	1520	767	116	77.8	0.15
FFQ Year 5	100	1393	680	162	1577	930	184	107.3	0.13
FFQ Year 6	48	1154	534	73	1424	705	270	119.4	0.04
FFQ Year 7	10	1219	298	21	1234	399	15	142.5	0.90
4DFR Baseline	96	1643	446	134	1748	460	105	60.8	0.06
4DFR Year 1	82	1400	412	110	1627	449	227	63.3	0.00
Total Fat (g)									
FFQ Baseline	751	81.6	41.0	1094	80.8	40.5	0.8	1.9	0.56
FFQ Year 1	617	44.5	27.3	914	64.3	41.2	19.8	1.9	0.00
FFQ Year 2	226	43.7	24.3	303	68.1	38.5	24.3	2.9	0.00
FFQ Year 3	129	52.2	32.1	193	65.9	34.9	13.6	3.8	0.00
FFQ Year 4	138	48.2	27.1	246	63.1	35.7	14.9	3.5	0.00
FFQ Year 5	100	45.7	31.2	162	66.8	46.1	21.1	5.2	0.00
FFQ Year 6	48	36.5	21.4	73	57.7	30.6	21.2	5.1	0.00
FFQ Year 7	10	40.2	15.0	21	50.8	17.1	10.6	6.3	0.12
4DFR Baseline	96	59.6	20.1	134	64.1	25.6	4.5	3.1	0.22
4DFR Year 1	82	36.4	17.7	110	58.9	24.5	22.5	3.2	0.00

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 106 (17%) Hispanic/Latino Intervention women had <=20% energy from fat at year 1.
[4] 45 (20%) Hispanic/Latino Intervention women had <=20% energy from fat at year 2.
[5] 14 (11%) Hispanic/Latino Intervention women had <=20% energy from fat at year 3.
[6] 14 (10%) Hispanic/Latino Intervention women had <=20% energy from fat at year 4.
[7] 17 (17%) Hispanic/Latino Intervention women had <=20% energy from fat at year 5.
[8] 7 (15%) Hispanic/Latino Intervention women had <=20% energy from fat at year 6.
[9] 2 (20%) Hispanic/Latino Intervention women had <=20% energy from fat at year 7.

Table 3.4 (continued)
Nutrient Intake Monitoring in Hispanic/Latino Women

Data as of: August 31, 2001

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	751	27.8	14.9	1094	27.7	15.1	0.1	0.7	0.65
FFQ Year 1[3]	617	15.0	9.8	914	21.7	14.3	6.7	0.7	0.00
FFQ Year 2[4]	226	14.4	8.4	303	23.0	14.2	8.6	1.1	0.00
FFQ Year 3[5]	129	17.4	12.1	193	22.0	12.5	4.7	1.4	0.00
FFQ Year 4[6]	138	15.6	9.6	246	21.1	12.8	5.5	1.2	0.00
FFQ Year 5[7]	100	15.0	10.4	162	22.6	16.1	7.6	1.8	0.00
FFQ Year 6[8]	48	11.5	7.4	73	19.7	11.2	8.2	1.8	0.00
FFQ Year 7[9]	10	13.4	6.1	21	17.0	6.6	3.6	2.5	0.15
4DFR Baseline	96	19.8	7.6	134	20.9	10.0	1.1	1.2	0.57
4DFR Year 1	82	11.5	6.8	110	19.4	8.9	7.9	1.2	0.00
Polyunsaturated Fat (g)									
FFQ Baseline	751	15.9	8.4	1094	15.7	8.2	0.2	0.4	0.48
FFQ Year 1	617	8.6	5.5	914	12.8	8.6	4.2	0.4	0.00
FFQ Year 2	226	8.7	5.3	303	13.4	8.2	4.7	0.6	0.00
FFQ Year 3	129	10.3	6.6	193	12.9	7.4	2.5	0.8	0.00
FFQ Year 4	138	9.4	5.6	246	12.3	7.2	2.9	0.7	0.00
FFQ Year 5	100	9.2	7.3	162	12.8	9.6	3.7	1.1	0.00
FFQ Year 6	48	7.6	4.6	73	11.7	7.3	4.1	1.2	0.00
FFQ Year 7	10	8.1	4.7	21	9.6	4.1	1.5	1.7	0.30
4DFR Baseline	96	11.5	4.6	134	13.4	6.2	1.9	0.7	0.02
4DFR Year 1	82	7.8	4.1	110	12.0	6.3	4.3	0.8	0.00
Fruits and Vegetables (servings)									
FFQ Baseline	748	3.0	1.9	1094	2.9	1.8	0.1	0.1	0.27
FFQ Year 1	614	4.2	2.3	914	3.1	1.9	1.0	0.1	0.00
FFQ Year 2	224	4.4	2.4	303	3.2	1.8	1.2	0.2	0.00
FFQ Year 3	128	4.6	2.9	193	3.3	2.0	1.3	0.3	0.00
FFQ Year 4	138	4.8	2.8	246	3.2	2.2	1.6	0.3	0.00
FFQ Year 5	99	4.7	2.4	162	3.3	2.2	1.5	0.3	0.00
FFQ Year 6	47	4.7	2.6	73	3.0	2.0	1.7	0.4	0.00
FFQ Year 7	10	4.2	4.0	21	2.8	1.8	1.4	1.0	0.39
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	748	5.5	3.3	1094	5.7	3.5	0.2	0.2	0.54
FFQ Year 1	614	5.1	3.3	914	4.8	3.4	0.3	0.2	0.06
FFQ Year 2	224	5.0	3.5	303	4.9	3.1	0.0	0.3	0.51
FFQ Year 3	128	5.1	3.0	193	4.6	2.9	0.4	0.3	0.31
FFQ Year 4	138	4.3	2.9	246	4.6	2.8	0.2	0.3	0.32
FFQ Year 5	99	4.5	3.2	162	4.9	3.7	0.4	0.4	0.38
FFQ Year 6	47	4.0	2.3	73	4.6	3.3	0.6	0.5	0.45
FFQ Year 7	10	4.1	1.6	21	4.7	2.5	0.6	0.9	0.80

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 106 (17%) Hispanic/Latino Intervention women had <=20% energy from fat at year 1.
[4] 45 (20%) Hispanic/Latino Intervention women had <=20% energy from fat at year 2.
[5] 14 (11%) Hispanic/Latino Intervention women had <=20% energy from fat at year 3.
[6] 14 (10%) Hispanic/Latino Intervention women had <=20% energy from fat at year 4.
[7] 17 (17%) Hispanic/Latino Intervention women had <=20% energy from fat at year 5.
[8] 7 (15%) Hispanic/Latino Intervention women had <=20% energy from fat at year 6.
[9] 2 (20%) Hispanic/Latino Intervention women had <=20% energy from fat at year 7.

Table 3.4 (continued)
Nutrient Intake Monitoring in White Women

Data as of: August 31, 2001

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	15872	38.7	5.0	23891	38.7	4.9	0.0	0.1	0.93
FFQ Year 1[3]	14898	24.6	7.3	22145	36.0	6.9	11.4	0.1	0.00
FFQ Year 2[4]	4828	25.8	7.5	7159	36.2	7.0	10.3	0.1	0.00
FFQ Year 3[5]	2562	27.2	7.8	3910	37.2	7.1	10.0	0.2	0.00
FFQ Year 4[6]	3543	28.0	8.1	5482	37.6	7.1	9.6	0.2	0.00
FFQ Year 5[7]	2684	28.4	8.3	4155	37.8	7.3	9.5	0.2	0.00
FFQ Year 6[8]	1700	29.0	8.0	2600	37.4	7.2	8.5	0.2	0.00
FFQ Year 7[9]	587	29.2	8.0	912	37.5	6.8	8.2	0.4	0.00
4DFR Baseline	442	32.6	6.5	669	32.6	6.7	0.1	0.4	0.88
4DFR Year 1	405	20.5	6.7	610	32.5	6.6	12.1	0.4	0.00
Total Energy (kcal)									
FFQ Baseline	15872	1795	688	23891	1797	677	2	7.0	0.62
FFQ Year 1	14898	1486	509	22145	1599	611	114	6.1	0.00
FFQ Year 2	4828	1493	497	7159	1591	598	97	10.4	0.00
FFQ Year 3	2562	1484	510	3910	1583	618	99	14.7	0.00
FFQ Year 4	3543	1459	513	5482	1586	618	127	12.5	0.00
FFQ Year 5	2684	1486	512	4155	1604	621	119	14.4	0.00
FFQ Year 6	1700	1478	534	2600	1554	611	76	18.1	0.00
FFQ Year 7	587	1497	530	912	1599	646	102	31.9	0.03
4DFR Baseline	442	1744	423	669	1741	448	4	26.9	0.68
4DFR Year 1	405	1461	332	610	1653	428	191	25.2	0.00
Total Fat (g)									
FFQ Baseline	15872	77.9	34.1	23891	77.9	33.4	0.0	0.3	0.65
FFQ Year 1	14898	40.9	20.6	22145	64.8	30.5	23.9	0.3	0.00
FFQ Year 2	4828	43.0	20.2	7159	64.9	30.1	21.9	0.5	0.00
FFQ Year 3	2562	45.3	22.4	3910	66.3	31.5	21.1	0.7	0.00
FFQ Year 4	3543	45.7	23.0	5482	67.1	31.8	21.4	0.6	0.00
FFQ Year 5	2684	47.2	23.8	4155	68.4	32.3	21.1	0.7	0.00
FFQ Year 6	1700	47.7	23.1	2600	65.4	31.3	17.7	0.9	0.00
FFQ Year 7	587	49.5	27.0	912	67.7	33.3	18.3	1.6	0.00
4DFR Baseline	442	64.2	23.9	669	64.0	23.5	0.2	1.5	0.81
4DFR Year 1	405	33.0	13.0	610	60.5	22.3	27.5	1.2	0.00

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 4373 (29%) White Intervention women had <=20% energy from fat at year 1.
[4] 1096 (23%) White Intervention women had <=20% energy from fat at year 2.
[5] 482 (19%) White Intervention women had <=20% energy from fat at year 3.
[6] 601 (17%) White Intervention women had <=20% energy from fat at year 4.
[7] 434 (16%) White Intervention women had <=20% energy from fat at year 5.
[8] 197 (12%) White Intervention women had <=20% energy from fat at year 6.
[9] 62 (11%) White Intervention women had <=20% energy from fat at year 7.

Table 3.4 (continued)
Nutrient Intake Monitoring in White Women

Data as of: August 31, 2001

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	15872	27.7	13.2	23891	27.6	12.8	0.1	0.1	0.95
FFQ Year 1[3]	14898	14.1	7.8	22145	22.9	11.6	8.8	0.1	0.00
FFQ Year 2[4]	4828	14.7	7.5	7159	22.9	11.4	8.1	0.2	0.00
FFQ Year 3[5]	2562	15.5	8.6	3910	23.4	12.0	7.9	0.3	0.00
FFQ Year 4[6]	3543	15.7	8.7	5482	23.7	12.2	8.0	0.2	0.00
FFQ Year 5[7]	2684	16.3	9.1	4155	24.3	12.5	8.0	0.3	0.00
FFQ Year 6[8]	1700	16.3	8.4	2600	23.2	12.1	6.9	0.3	0.00
FFQ Year 7[9]	587	17.2	10.1	912	24.0	12.8	6.9	0.6	0.00
4DFR Baseline	442	21.7	9.2	669	21.6	9.1	0.1	0.6	0.64
4DFR Year 1	405	10.4	4.7	610	20.2	8.3	9.8	0.5	0.00
Polyunsaturated Fat (g)									
FFQ Baseline	15872	15.2	7.4	23891	15.2	7.3	0.0	0.1	0.47
FFQ Year 1	14898	7.7	4.1	22145	12.4	6.4	4.7	0.1	0.00
FFQ Year 2	4828	8.1	4.1	7159	12.3	6.2	4.2	0.1	0.00
FFQ Year 3	2562	8.6	4.4	3910	12.7	6.5	4.1	0.1	0.00
FFQ Year 4	3543	8.8	4.6	5482	12.8	6.6	4.1	0.1	0.00
FFQ Year 5	2684	9.0	4.8	4155	13.1	6.7	4.1	0.1	0.00
FFQ Year 6	1700	9.3	4.9	2600	12.5	6.3	3.2	0.2	0.00
FFQ Year 7	587	9.4	5.6	912	12.9	6.8	3.5	0.3	0.00
4DFR Baseline	442	12.9	5.5	669	13.2	5.7	0.3	0.3	0.51
4DFR Year 1	405	7.1	3.1	610	12.4	5.6	5.3	0.3	0.00
Fruits and Vegetables (servings)									
FFQ Baseline	15810	3.7	1.8	23818	3.7	1.8	0.0	0.0	0.17
FFQ Year 1	14829	5.2	2.3	22070	3.9	2.0	1.2	0.0	0.00
FFQ Year 2	4810	5.2	2.3	7132	4.0	2.0	1.3	0.0	0.00
FFQ Year 3	2557	5.3	2.4	3897	4.0	2.0	1.3	0.1	0.00
FFQ Year 4	3535	5.2	2.4	5470	3.9	2.0	1.3	0.0	0.00
FFQ Year 5	2665	5.2	2.4	4133	4.0	2.1	1.3	0.1	0.00
FFQ Year 6	1686	5.2	2.5	2586	3.9	2.0	1.4	0.1	0.00
FFQ Year 7	580	5.1	2.3	910	3.9	1.9	1.3	0.1	0.00
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	15808	4.7	2.4	23817	4.8	2.4	0.0	0.0	0.21
FFQ Year 1	14826	5.1	2.6	22062	4.2	2.2	0.9	0.0	0.00
FFQ Year 2	4809	5.0	2.5	7127	4.1	2.1	0.8	0.0	0.00
FFQ Year 3	2556	4.7	2.5	3892	4.0	2.1	0.7	0.1	0.00
FFQ Year 4	3532	4.5	2.4	5460	3.9	2.1	0.6	0.0	0.00
FFQ Year 5	2663	4.5	2.2	4129	3.9	2.1	0.5	0.1	0.00
FFQ Year 6	1686	4.5	2.5	2584	3.8	2.1	0.6	0.1	0.00
FFQ Year 7	580	4.4	2.2	910	3.9	2.1	0.5	0.1	0.00

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 4373 (29%) White Intervention women had <=20% energy from fat at year 1.
[4] 1096 (23%) White Intervention women had <=20% energy from fat at year 2.
[5] 482 (19%) White Intervention women had <=20% energy from fat at year 3.
[6] 601 (17%) White Intervention women had <=20% energy from fat at year 4.
[7] 434 (16%) White Intervention women had <=20% energy from fat at year 5.
[8] 197 (12%) White Intervention women had <=20% energy from fat at year 6.
[9] 62 (11%) White Intervention women had <=20% energy from fat at year 7.

Table 3.4 (continued)
Nutrient Intake Monitoring in Other/Unspecified Women

Data as of: August 31, 2001

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	265	39.1	5.3	394	39.2	5.1	0.1	0.4	0.79
FFQ Year 1[3]	240	27.7	8.0	354	35.9	7.7	8.3	0.7	0.00
FFQ Year 2[4]	79	27.2	7.9	123	37.3	6.9	10.2	1.1	0.00
FFQ Year 3[5]	46	29.1	7.4	55	37.9	8.1	8.8	1.6	0.00
FFQ Year 4[6]	57	29.5	8.5	93	37.3	7.4	7.8	1.3	0.00
FFQ Year 5[7]	33	28.4	8.4	42	36.6	7.1	8.2	1.8	0.00
FFQ Year 6[8]	13	31.1	6.7	33	39.0	7.7	7.9	2.4	0.00
FFQ Year 7[9]	4	32.0	8.6	9	35.6	9.1	3.6	5.4	0.52
4DFR Baseline	17	32.2	5.5	29	32.8	5.6	0.6	1.7	0.71
4DFR Year 1	13	22.8	8.9	24	33.6	6.5	10.8	2.6	0.00
Total Energy (kcal)									
FFQ Baseline	265	1796	775	394	1726	770	70	61.3	0.23
FFQ Year 1	240	1506	628	354	1501	639	4	53.1	0.66
FFQ Year 2	79	1464	584	123	1572	674	108	92.3	0.33
FFQ Year 3	46	1464	598	55	1496	729	33	134.4	0.81
FFQ Year 4	57	1391	617	93	1525	668	133	109.2	0.29
FFQ Year 5	33	1545	580	42	1423	589	122	136.1	0.20
FFQ Year 6	13	1818	551	33	1504	754	314	230.6	0.03
FFQ Year 7	4	1331	825	9	1662	446	331	345.4	0.35
4DFR Baseline	17	1504	288	29	1693	405	189	112.0	0.10
4DFR Year 1	13	1334	469	24	1542	335	207	133.0	0.13
Total Fat (g)									
FFQ Baseline	265	79.0	39.4	394	75.9	38.4	3.1	3.1	0.31
FFQ Year 1	240	46.7	28.0	354	60.7	31.5	14.0	2.5	0.00
FFQ Year 2	79	44.9	29.0	123	66.7	35.1	21.8	4.7	0.00
FFQ Year 3	46	46.2	21.0	55	63.6	36.2	17.4	6.0	0.00
FFQ Year 4	57	46.9	31.8	93	64.5	34.0	17.7	5.6	0.00
FFQ Year 5	33	49.5	27.0	42	59.4	29.9	9.9	6.7	0.26
FFQ Year 6	13	64.7	29.8	33	66.7	42.6	2.0	12.9	0.87
FFQ Year 7	4	42.3	13.2	9	64.4	19.5	22.2	10.8	0.08
4DFR Baseline	17	54.4	16.8	29	61.8	17.4	7.4	5.2	0.18
4DFR Year 1	13	33.7	19.1	24	57.9	17.3	24.2	6.2	0.00

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 38 (16%) Other/Unspecified Intervention women had <=20% energy from fat at year 1.
[4] 16 (20%) Other/Unspecified Intervention women had <=20% energy from fat at year 2.
[5] 5 (11%) Other/Unspecified Intervention women had <=20% energy from fat at year 3.
[6] 9 (16%) Other/Unspecified Intervention women had <=20% energy from fat at year 4.
[7] 6 (18%) Other/Unspecified Intervention women had <=20% energy from fat at year 5.
[8] 0 (0%) Other/Unspecified Intervention women had <=20% energy from fat at year 6.
[9] 0 (0%) Other/Unspecified Intervention women had <=20% energy from fat at year 7.

Table 3.4 (continued)
Nutrient Intake Monitoring in Other/Unspecified Women

Data as of: August 31, 2001

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	265	27.2	14.6	394	26.3	14.2	0.9	1.1	0.47
FFQ Year 1[3]	240	15.5	9.4	354	20.9	11.7	5.5	0.9	0.00
FFQ Year 2[4]	79	15.3	10.7	123	23.2	12.6	7.9	1.7	0.00
FFQ Year 3[5]	46	15.3	7.9	55	21.3	13.2	6.0	2.2	0.00
FFQ Year 4[6]	57	15.6	10.7	93	22.5	12.4	6.9	2.0	0.00
FFQ Year 5[7]	33	15.9	9.1	42	19.9	10.5	4.0	2.3	0.17
FFQ Year 6[8]	13	22.5	12.9	33	22.5	15.7	0.0	4.9	0.92
FFQ Year 7[9]	4	15.4	4.4	9	24.4	8.1	9.0	4.4	0.09
4DFR Baseline	17	17.6	6.7	29	21.0	7.2	3.4	2.1	0.10
4DFR Year 1	13	11.3	8.7	24	18.9	5.7	7.6	2.4	0.00
Polyunsaturated Fat (g)									
FFQ Baseline	265	15.9	8.7	394	15.0	8.6	0.9	0.7	0.19
FFQ Year 1	240	9.1	6.0	354	11.9	6.8	2.8	0.5	0.00
FFQ Year 2	79	8.4	5.6	123	12.8	7.8	4.5	1.0	0.00
FFQ Year 3	46	9.0	4.1	55	13.1	8.0	4.1	1.3	0.00
FFQ Year 4	57	9.3	6.8	93	12.6	7.7	3.3	1.2	0.00
FFQ Year 5	33	10.4	5.8	42	11.9	6.5	1.5	1.4	0.53
FFQ Year 6	13	12.6	5.4	33	13.4	8.7	0.8	2.6	0.88
FFQ Year 7	4	6.8	2.6	9	10.7	3.7	3.9	2.1	0.09
4DFR Baseline	17	11.7	3.7	29	12.5	4.4	0.8	1.3	0.59
4DFR Year 1	13	6.6	3.1	24	11.8	4.3	5.2	1.4	0.00
Fruits and Vegetables (servings)									
FFQ Baseline	264	3.7	2.0	393	3.4	2.0	0.3	0.2	0.04
FFQ Year 1	239	4.9	2.4	353	3.6	2.1	1.3	0.2	0.00
FFQ Year 2	78	5.0	2.3	123	3.9	2.3	1.1	0.3	0.00
FFQ Year 3	46	5.0	2.6	55	3.7	1.9	1.3	0.5	0.01
FFQ Year 4	56	4.9	2.7	93	4.0	2.2	1.0	0.4	0.07
FFQ Year 5	33	5.6	2.7	42	3.7	2.4	1.9	0.6	0.00
FFQ Year 6	12	6.2	2.3	33	4.2	2.4	2.0	0.8	0.00
FFQ Year 7	4	4.2	2.9	9	7.0	3.4	2.9	2.0	0.26
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	264	4.8	2.7	393	4.7	2.7	0.1	0.2	0.71
FFQ Year 1	239	5.0	3.0	353	4.2	2.4	0.9	0.2	0.00
FFQ Year 2	78	4.7	2.4	123	4.2	2.3	0.4	0.3	0.31
FFQ Year 3	46	4.7	3.0	55	4.2	2.9	0.4	0.6	0.48
FFQ Year 4	56	4.1	2.3	93	4.0	2.2	0.2	0.4	0.60
FFQ Year 5	33	4.9	2.6	42	3.9	2.3	1.0	0.6	0.11
FFQ Year 6	12	5.0	2.1	33	3.4	2.2	1.6	0.7	0.00
FFQ Year 7	4	4.7	5.0	9	4.1	2.0	0.6	1.9	0.84

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 38 (16%) Other/Unspecified Intervention women had <=20% energy from fat at year 1.
[4] 16 (20%) Other/Unspecified Intervention women had <=20% energy from fat at year 2.
[5] 5 (11%) Other/Unspecified Intervention women had <=20% energy from fat at year 3.
[6] 9 (16%) Other/Unspecified Intervention women had <=20% energy from fat at year 4.
[7] 6 (18%) Other/Unspecified Intervention women had <=20% energy from fat at year 5.
[8] 0 (0%) Other/Unspecified Intervention women had <=20% energy from fat at year 6.
[9] 0 (0%) Other/Unspecified Intervention women had <=20% energy from fat at year 7.

Table 3.5
Control - Intervention Difference in % Energy from Fat in WHI DM Participants
Study Subject Characteristics and Session Participation from FFQs Collected in the Last Year[1]

Data as of: August 31, 2001

	Model Including Attendance				Model Including Completion				Model Including Fat Scores			
	N	C – I (%)	R^2	(ΔR^2) for Inclusion	N	C – I (%)	R^2	(ΔR^2) for Inclusion	N	C – I (%)	R^2	(ΔR^2) for Inclusion
Demographics			22.0%				22.0%				22.0%	
Age												
60-69	9263				9263				9263			
50-54 vs. 60-69	3217	0.82 *			3217	0.91 **			3217	0.98 **		
55-59 vs. 60-69	4923	0.53 *			4923	0.52			4923	0.63 *		
70-79 vs. 60-69	3198	-1.12 **			3198	-1.04 **			3198	-1.07 **		
Ethnicity												
White	17011				17011				17011			
American Indian vs. White	88	0.05			88	-0.02			88	0.28		
Asian/Pacific Islander vs. White	512	-0.14			512	-0.33			512	-0.33		
Black vs. White	2071	-1.23 **			2071	-1.29 **			2071	-0.84 *		
Hispanic vs. White	681	-1.23			681	-1.16			681	-0.99		
Other Minority vs. White	238	-0.61			238	-0.63			238	-0.54		
Education												
Post H.S.	16129				16129				16129			
0-8 Years vs. Post H.S.	191	-1.37			191	-1.27			191	-1.31		
Some H.S. or Diploma vs. Post H.S.	4281	0.01			4281	0.16			4281	0.08		
Family Income												
≥75K	3642				3642				3642			
<20K vs. ≥75K	3562	-0.36			3562	-0.22			3562	-0.10		
20-35K vs. ≥75K	4916	-0.55			4916	-0.38			4916	-0.31		
35-50K vs. ≥75K	4289	-0.29			4289	-0.23			4289	-0.13		
50-75K vs. ≥75K	4192	0.16			4192	0.20			4192	0.30		
HRT Randomized												
No	17286				17286				17286			
Yes vs. No	3315	0.76 **			3315	0.86 **			3315	0.78 **		
Visit			23.3%	(1.3%)			23.3%	(1.3%)			23.3%	(1.3%)
Visit Year												
AV-3	2645				2645				2645			
AV-2 vs. AV-3	59	-0.63			59	-0.11			59	-0.15		
AV-4 vs. AV-3	6492	0.13			6492	0.01			6492	0.06		
AV-5 vs. AV-3	5973	0.07			5973	-0.06			5973	0.09		
AV-6 vs. AV-3	3831	-0.52			3831	-0.71 *			3831	-0.60		
AV-7 vs. AV-3	1601	-0.42			1601	-0.81			1601	-0.59		
Clinic Effect			27.2%	(3.9%)			27.2%	(3.9%)			27.2%	(3.9%)
Intervention Participation												
# Sessions Attended in Previous 12 Months			31.1%	(3.9%)								
None	14658											
1 vs. None	1007	4.03 **										
2 vs. None	1473	5.57 **										
3 vs. None	1827	6.41 **										
4+ vs. None	1636	7.32 **										
# Sessions Completed in Previous 12 Months							31.9%	(4.7%)				
None					13756							
1 vs. None					439	2.92 **						
2 vs. None					576	5.01 **						
3 vs. None					1263	6.62 **						
4+ vs. None					4567	8.58 **						
# Fat Scores Provided in Previous 12 Months											32.6%	(5.4%)
None									14748			
1 vs. None									820	3.86 **		
2 vs. None									768	5.06 **		
3 vs. None									1253	6.55 **		
4+ vs. None									3012	8.23 **		

[1] Model adjusted for clinic effects.
* P-value < 0.05 from a two-sided test.
** P-value < 0.01 from a two-sided test.

Table 3.6
Body Weight

Data as of: August 31, 2001

Body Weight (kg)[1]	Intervention			Control			Difference		
	N	Mean	S.D.	N	Mean	S.D.	Mean[2]	S.E.	p-value
All Participants									
Baseline	19524	76.8	16.7	29271	76.7	16.6	-0.1	0.2	0.36
Year 1	18146	74.4	16.8	26681	76.3	16.8	1.9	0.2	0.00
Year 2	16696	75.4	17.2	25044	76.7	16.9	1.3	0.2	0.00
Year 3	16640	75.7	17.1	25341	76.8	16.8	1.1	0.2	0.00
Year 4	12850	75.9	17.1	19814	76.7	16.7	0.8	0.2	0.00
Year 5	7845	76.1	16.9	12045	76.7	16.5	0.6	0.2	0.01
Year 6	3657	75.9	16.5	5630	76.0	15.7	0.2	0.3	0.63
Year 7	1066	75.1	16.3	1698	75.1	15.0	0.4	0.5	0.99
Participants Aged 70-79									
Baseline	3246	73.0	14.7	4870	72.9	14.5	-0.1	0.3	0.82
Year 1	3009	70.7	15.2	4485	72.7	15.4	1.9	0.4	0.00
Year 2	2784	71.1	15.1	4173	72.6	15.3	1.6	0.4	0.00
Year 3	2750	71.1	15.4	4185	72.2	14.8	1.1	0.4	0.00
Year 4	1946	70.7	14.7	2992	71.5	14.3	0.8	0.4	0.06
Year 5	1019	70.2	14.7	1575	71.0	14.2	0.8	0.6	0.18
Year 6	451	69.9	14.4	720	70.7	13.8	0.8	0.8	0.32
Year 7	114	69.2	16.7	199	69.6	14.7	0.4	0.5	0.82
Participants with Revised Fat Gram Goals[3]									
Baseline	15848	77.0	17.0	23738	77.0	16.9	0.0	0.2	0.80
Year 1	14688	74.6	17.1	21611	76.6	17.1	2.0	0.2	0.00
Year 2	13433	75.5	17.4	20200	77.0	17.2	1.5	0.2	0.00
Year 3	13443	75.8	17.3	20507	77.0	17.0	1.2	0.2	0.00
Year 4	9776	76.0	17.1	15103	76.9	16.8	1.0	0.2	0.00
Year 5	4869	76.2	17.2	7455	77.0	16.7	0.8	0.3	0.01
Year 6	720	75.3	16.3	1043	76.2	15.9	0.9	0.8	0.23
Year 7	4	75.4	15.8	5	64.0	12.3	0.4	0.5	0.28

[1] Shown for 30 <= weight (kg) <= 220.
[2] Control – Intervention.
[3] For revised fat gram goals:
Intervention group is defined as women randomized to Intervention after 6/15/95 that have revised fat gram goals.
Control group is defined as women randomized to Control after 6/15/95.

Table 3.6 (continued)
Body Weight by Race/Ethnicity

Data as of: August 31, 2001

Body Weight (kg)[1]	Intervention N	Intervention Mean	Intervention S.D.	Control N	Control Mean	Control S.D.	Difference Mean[2]	Difference S.E.	Difference p-value
American Indian/Alaskan									
Baseline	87	77.8	14.4	114	80.9	17.0	3.1	2.3	0.17
Year 1	74	75.6	15.0	93	81.3	16.9	5.7	2.5	0.02
Year 2	66	76.9	18.7	91	83.5	18.1	6.6	3.0	0.03
Year 3	67	75.5	15.5	94	83.6	17.6	8.1	2.7	0.00
Year 4	60	76.7	16.1	74	84.5	18.8	7.8	3.1	0.01
Year 5	38	77.4	16.0	47	85.9	17.7	8.6	3.7	0.02
Year 6	15	77.4	17.6	17	80.3	17.9	2.8	6.3	0.66
Year 7	3	74.9	11.7	2	72.6	10.0	0.4	0.5	0.83
Asian/Pacific Islander									
Baseline	431	63.4	13.2	674	63.4	14.4	-0.1	0.9	0.93
Year 1	414	62.5	14.7	636	62.8	12.9	0.3	0.9	0.78
Year 2	392	62.7	14.1	615	63.0	12.4	0.3	0.8	0.73
Year 3	392	63.2	13.5	612	63.9	14.7	0.7	0.9	0.42
Year 4	274	62.5	12.0	464	63.6	13.5	1.1	1.0	0.27
Year 5	147	61.6	11.6	236	62.6	11.9	1.1	1.2	0.38
Year 6	35	61.3	9.5	50	63.1	10.4	1.9	2.2	0.39
Year 7	8	75.1	41.2	7	61.5	9.6	0.4	0.5	0.39
Black/African American									
Baseline	2133	85.3	18.2	3126	85.1	18.5	-0.1	0.5	0.79
Year 1	1890	84.3	19.3	2662	84.9	19.0	0.6	0.6	0.28
Year 2	1715	84.9	18.8	2504	85.3	19.0	0.4	0.6	0.53
Year 3	1688	85.1	19.2	2496	85.2	18.8	0.1	0.6	0.92
Year 4	1276	85.3	19.2	1894	85.8	18.4	0.5	0.7	0.47
Year 5	774	85.2	19.2	1169	85.4	18.7	0.2	0.9	0.80
Year 6	339	84.1	18.3	481	84.1	17.1	0.0	1.2	0.98
Year 7	57	82.3	17.4	84	82.0	17.9	0.4	0.5	0.93
Hispanic/Latino									
Baseline	750	75.2	16.0	1094	73.7	15.2	-1.5	0.7	0.05
Year 1	638	74.2	16.6	935	73.2	15.6	-1.0	0.8	0.23
Year 2	570	74.4	16.1	863	73.9	15.8	-0.4	0.9	0.60
Year 3	545	75.3	16.9	863	74.3	16.5	-1.0	0.9	0.27
Year 4	417	75.8	17.5	667	73.9	14.2	-1.9	1.0	0.06
Year 5	234	75.5	16.6	375	74.6	14.3	-1.0	1.3	0.46
Year 6	80	74.0	15.4	127	70.3	12.5	-3.7	2.0	0.07
Year 7	26	75.7	11.3	41	72.0	14.5	0.4	0.5	0.24
White									
Baseline	265	78.3	18.4	394	76.4	16.8	0.0	0.2	0.18
Year 1	239	77.6	20.4	345	77.0	18.0	2.4	0.2	0.71
Year 2	205	76.3	18.6	324	77.3	18.6	1.6	0.2	0.56
Year 3	207	76.9	17.6	320	77.1	18.2	1.3	0.2	0.88
Year 4	146	76.2	19.2	236	75.9	16.1	0.9	0.2	0.87
Year 5	70	77.3	17.2	118	76.9	18.2	0.6	0.3	0.88
Year 6	26	82.4	17.0	55	76.2	15.5	0.4	0.5	0.12
Year 7	9	81.3	20.3	16	76.7	17.9	0.4	0.5	0.58
Other/Unspecified									
Baseline	15858	76.1	16.1	23869	76.1	15.9	0.0	0.2	0.87
Year 1	14891	73.5	15.9	22010	75.8	16.2	2.3	0.2	0.00
Year 2	13748	74.6	16.6	20647	76.2	16.3	1.6	0.2	0.00
Year 3	13741	74.9	16.5	20956	76.2	16.2	1.3	0.2	0.00
Year 4	10677	75.1	16.4	16479	76.2	16.2	1.0	0.2	0.00
Year 5	6582	75.3	16.2	10100	76.0	16.0	0.7	0.3	0.01
Year 6	3162	75.1	16.0	4900	75.5	15.4	0.4	0.4	0.31
Year 7	963	74.6	15.9	1548	74.8	14.8	0.4	0.5	0.69

[1] Shown for 30 <= weight (kg) <= 220.
[2] Control – Intervention.

Table 3.7
Reasons for Stopping DM[1]

Data as of: August 31, 2001

Reasons[2]	(N = 2173)	
Personal/family		
Demands of work	253	11.6%
Family illness, emergency, or other family demands[3]	293	13.5%
Financial problems	8	0.4%
Lack of cooperation/support from family/friends[4]	39	1.8%
Living in nursing home	20	0.9%
Issues of interest in study[5]	228	10.5%
Travel		
Too far to CC	124	5.7%
Moved out of area or refuses to be followed at another CC	12	0.6%
Other Travel Issues[6]	64	2.9%
Visits & Procedures		
Doesn't like visits/calls	46	2.1%
Doesn't like required forms or safety procedures[7]	45	2.1%
Problems with other procedures[8]	14	0.6%
Worried about health effects of medical tests/procedures	3	0.1%
Wants test results[9]	0	0.0%
Problems with the CC[10]	29	1.3%

(continues)

[1] Does not include reasons reported by women who stopped and later restarted DM Intervention.
[2] Multiple reasons may be reported for a woman.
[3] Combines "Family illness, emergency or other family demands", "Death in the family or of a close friend", and "Caregiver responsibilities demanding time, effort, lifestyle changes".
[4] Combines "Lack of cooperation/support from family and/or friends" and "Family/friends request that she withdraw".
[5] Combines "Conflicting priorities other than work or family", "Feels discouraged regarding participation overall", "Loss of interest, boredom", "Feels it is not an important study", and "In another study in conflict with WHI intervention".
[6] Combines "Transportation problems (other than distance)", "Traffic", "Parking at CC", and "CC neighborhood/safety".
[7] Combines "Doesn't like filling out forms (other than those required for safety)", and "Doesn't like required safety forms and/or procedures".
[8] Combines "Doesn't like mammograms", "Cost of mammograms", "Doesn't like having blood drawn", "Doesn't like ECG", "Doesn't like gynecologic procedures" and "Doesn't like other procedures (other than those required for safety)".
[9] Combines "Wants results of blood analyses", and "Wants results of bone mineral density measurement".
[10] Combines "Problem with the CC", "Problem with CC staff person (other than DM Group Nutritionist)", and "Staff change/turnover".

Table 3.7 (continued)
Reasons for Stopping DM[1]

Data as of: August 31, 2001

Reasons[2]	(N = 2173)	
Symptoms		
GI Problems[3]	0	0.0%
Hair/Skin Changes	0	0.0%
Weight loss/gain	5	0.2%
HRT Related Symptoms[4]	3	0.1%
Other[5]	7	0.3%
Health Conditions		
Disease and/or health conditions[6]	62	2.9%
Communication difficulties[7]	34	1.6%
Intervention		
Doesn't like randomized nature of intervention	9	0.4%
Expected some benefit from intervention	35	1.6%
Feels guilty/unhappy or like a failure for not meeting study goals	14	0.6%
Pill Issues[8]	4	0.2%
CaD Issues[9]	0	0.0%
HRT Issues[10]	1	<0.1%
Problem with DM group nutritionist or group members	33	1.5%
Doesn't like attending DM intervention classes	54	2.5%
Doesn't like self-monitoring	39	1.8%
Doesn't like budgeting fat grams	2	0.1%
Health concerns regarding long-term risk/benefits of low fat diet	13	0.6%
Unhappy that not losing weight	18	0.8%
Not in control of meal preparation	11	0.5%
Too difficult to meet or maintain dietary goals	37	1.7%
Doesn't like eating low fat diet	22	1.0%
Doesn't like eating 5 vegetables/fruits per day	1	<0.1%
Doesn't like eating 6 grains per day	7	0.3%
Feels fat gram goal is unrealistic	5	0.2%
Eating pattern conflicts with personal health beliefs	22	1.0%
Other Health Issues		
Worried about costs if adverse effects occur	1	<0.1%
Expected more health care	15	0.7%
Advised not to participate by health care provider[11]	24	1.1%
Study conflicts with other health issues[12]	29	1.3%
Other		
Other reasons not listed above	465	21.4%
Refuses to give a reason	96	4.4%

[1] Does not include reasons reported by women who stopped and later restarted DM Intervention.
[2] Multiple reasons may be reported for a woman.
[3] Combines "Bloating/Gas", "Constipation", and "Other gastrointestinal problems".
[4] Combines "Vaginal bleeding", "Breast tenderness", "Other breast changes", "Vaginal changes (e.g., dryness)", and "Hot flashes/night sweats".
[5] Combines "Headaches", "Low energy/too tired", "Possible allergic reaction", and "Other symptoms not listed above".
[6] Combines "Breast cancer", "Complex or atypical hyperplasia", "Endometrial cancer", "Deep vein thrombosis", "Pulmonary embolism", "Gallbladder disease", "Hypercalcemia", "Kidney failure/dialysis", "Renal calculi", "High triglycerides (> 1000 mg/dl)", "Malignant melanoma", "Meningioma", "Heart attack", "Stroke", "Arthritis", "Diabetes", "Depression", "Cholesterol (high or concern about levels)", "Osteoporosis", and "Other health conditions not listed above".
[7] Combines "Communication problem", "Loss of vision and/or hearing", and "Cognitive/memory changes".
[8] Combines "Doesn't like taking pills", "Doesn't like taste of pills", "Unable to swallow pills", and "Takes too many pills".
[9] Combines "Wants to take her own calcium", "Feels diet is already sufficient in calcium/Vitamin D", "Taking more than the maximum allowable IU of Vit D", and "Taking Calcitriol".
[10] Combines "Has made a personal decision to go on active HRT", "Has made a personal decision that she does not want to be on HRT", "Advised to go on active HRT by health care provider", "Advised to not be on active HRT by health care provider", "Has made a personal decision to go on SERM (e.g., Evista/raloxifene, tamoxifen)", "Advised to go on SERM (e.g., Evista/raloxifene, tamoxifen) by health care provider", and "Taking testosterone medications".
[11] Combines "Advised not to participate by health care provider" and "Advised not to participate by health care provider for other reason".
[12] Combines "Study conflicts with health care needs" and "Study conflicts with other health issues".

Table 3.8
Reasons for Stopping DM by Age at Screening and Race/Ethnicity[1]

Data as of August 31, 2001

			Age at Screening							
	All (N = 19,542)		50 – 54 (N = 2,783)		55 –59 (N = 4,424)		60 –69 (N = 9,087)		70 –79 (N = 3,248)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping Intervention	2173	11.1%	373	13.4%	504	11.4%	860	9.5%	436	13.4%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Family illness, emergency, or other family demands[5]	293	13.5%	46	12.3%	74	14.7%	116	13.5%	57	13.1%
Demands of work	253	11.6%	82	22.0%	73	14.5%	83	9.7%	15	3.4%
Issues of interest in study[6]	228	10.5%	40	10.7%	61	12.1%	88	10.2%	39	8.9%
Too far to CC	124	5.7%	27	7.2%	34	6.7%	48	5.6%	15	3.4%
Other ("Other reasons not listed above")	465	21.4%	83	22.3%	128	25.4%	181	21.0%	73	16.7%

	Race/Ethnicity											
	American Indian/ Alaskan Native (N = 88)		Asian/Pacific Islander (N = 431)		Black/African American (N = 2,135)		Hispanic/Latino (N = 751)		White (N = 15,872)		Other/ Unspecified (N = 265)	
	N	%[7]	N	%[7]	N	%[7]	N	%[7]	N	%[7]	N	%[7]
Women Stopping Intervention	17	19.3%	45	10.4%	300	14.1%	156	20.8%	1612	10.2%	43	16.2%
REASONS FOR STOPPING[3]	N	%[8]	N	%[8]	N	%[8]	N	%[8]	N	%[8]	N	%[8]
Family illness, emergency, or other family demands[5]	2	11.8%	3	6.7%	36	12.0%	27	17.3%	219	13.6%	6	14.0%
Demands of work	1	5.9%	5	11.1%	48	16.0%	17	10.9%	179	11.1%	3	7.0%
Issues of interest in study[6]	3	17.6%	4	8.9%	35	11.7%	9	5.8%	173	10.7%	4	9.3%
Too far to CC	2	11.8%	3	6.7%	8	2.7%	7	4.5%	103	6.4%	1	2.3%
Other ("Other reasons not listed above")	4	23.5%	9	20.0%	49	16.3%	51	32.7%	343	21.3%	9	20.9%

[1] Does not include reasons reported by women who stopped and later restarted DM intervention.

[2] Percentages are of DM intervention participants in the same age category.

[3] Multiple reasons may be reported for a woman.

[4] Percentages are of DM intervention participants in the same age category who stopped DM intervention.

[5] Combines "Family illness, emergency or other family demands", "Death in the family or of a close friend", and "Caregiver responsibilities demanding time, effort, lifestyle changes".

[6] Combines "Conflicting priorities other than work or family", "Feels discouraged regarding participation overall", "Loss of interest, boredom", "Feels it is not an important study", and "In another study in conflict with WHI intervention".

[7] Percentages are of DM intervention participants in the same race/ethnicity category.

[8] Percentages are of DM intervention participants in the same race/ethnicity category who stopped DM intervention.

Table 3.9
Blood Specimen Analysis: DM Participants

Data as of: August 31, 2001

	N	Mean[1]	S.D.[1]
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	2396	0.08	0.08
AV-1	2398	0.08	0.07
AV-1 – Baseline	2393	0.00	0.06
Beta-Carotene (µg/ml)			
Baseline	2396	0.30	0.29
AV-1	2398	0.31	0.29
AV-1 – Baseline	2393	0.00	0.22
Alpha-tocopherol (µg/ml)			
Baseline	2396	16.19	6.97
AV-1	2398	16.95	7.52
AV-1 – Baseline	2393	0.75	5.45
Gamma-tocopherol (µg/ml)			
Baseline	2396	2.20	1.42
AV-1	2397	1.84	1.30
AV-1 – Baseline	2392	-0.36	0.93
Beta-Cryptoxanthine (µg/ml)			
Baseline	2396	0.09	0.07
AV-1	2397	0.09	0.07
AV-1 - Baseline	2392	0.00	0.06
Lycopene (µg/ml)			
Baseline	2396	0.41	0.19
AV-1	2398	0.41	0.19
AV-1 – Baseline	2393	-0.01	0.16
Lutein and Zeaxanthin (µg/ml)			
Baseline	2396	0.22	0.11
AV-1	2398	0.22	0.10
AV-1 – Baseline	2393	0.00	0.07
Retinol (µg/ml)			
Baseline	2396	0.61	0.15
AV-1	2398	0.62	0.15
AV-1 – Baseline	2393	0.00	0.10

(continues)

[1] Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.

Table 3.9 (continued)
Blood Specimen Analysis: DM Participants

Data as of: August 31, 2001

	N	Mean[1]	S.D.[1]
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	2323	130.86	32.76
AV-1	2304	130.69	32.81
AV-1 - Baseline	2248	-0.24	22.37
Factor VII C (%)[2]			
Baseline	2280	129.48	30.69
AV-1	2273	127.07	30.22
AV-1 - Baseline	2184	-2.83	22.32
Fibrinogen (mg/dl)			
Baseline	2317	300.17	61.25
AV-1	2298	297.80	60.57
AV-1 - Baseline	2237	-2.32	49.75
Hormones/Other			
Glucose (mg/dl)			
Baseline	2396	100.21	26.69
AV-1	2390	98.94	26.43
AV-1 - Baseline	2385	-1.26	19.04
Insulin (μIU/ml)			
Baseline	2344	11.51	7.41
AV-1	2338	11.23	10.41
AV-1 - Baseline	2290	-0.29	8.57

(continues)

[1] Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.
[2] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.9 (continued)
Blood Specimen Analysis: DM Participants

Data as of: August 31, 2001

	N	Mean[1]	S.D.[1]
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	2395	156.02	85.74
AV-1	2396	158.55	86.46
AV-1 – Baseline	2391	2.34	55.06
Total Cholesterol (mg/dl)			
Baseline	2395	224.27	37.88
AV-1	2396	217.74	37.49
AV-1 – Baseline	2391	-6.58	26.73
LDL-C (mg/dl)			
Baseline	2352	133.63	34.81
AV-1	2354	126.71	34.21
AV-1 – Baseline	2328	-6.81	23.83
HDL-C (mg/dl)			
Baseline	2389	59.60	15.71
AV-1	2394	59.46	15.32
AV-1 – Baseline	2384	-0.10	8.81
HDL-2 (mg/dl)			
Baseline	2335	18.74	8.26
AV-1	2353	19.03	8.40
AV-1 – Baseline	2299	0.30	4.99
HDL-3 (mg/dl)			
Baseline	2337	41.00	9.05
AV-1	2354	40.48	8.58
AV-1 – Baseline	2302	-0.52	5.56
Lp(a) (mg/dl)			
Baseline	2364	25.72	26.57
AV-1	2365	25.13	26.22
AV-1 – Baseline	2335	-0.57	10.11

[1] Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.

Table 3.10
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: August 31, 2001

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	57	0.06	0.04
AV-1	57	0.06	0.05
AV-1 – Baseline	57	0.01	0.04
Beta-Carotene (µg/ml)			
Baseline	57	0.27	0.26
AV-1	57	0.27	0.31
AV-1 – Baseline	57	0.00	0.20
Alpha-tocopherol (µg/ml)			
Baseline	57	17.25	8.21
AV-1	57	18.25	9.62
AV-1 – Baseline	57	1.00	5.58
Gamma-tocopherol (µg/ml)			
Baseline	57	2.21	1.26
AV-1	57	1.80	1.23
AV-1 – Baseline	57	-0.41	0.84
Beta-Cryptoxanthine (µg/ml)			
Baseline	57	0.06	0.04
AV-1	57	0.07	0.04
AV-1 - Baseline	57	0.01	0.04
Lycopene (µg/ml)			
Baseline	57	0.35	0.15
AV-1	57	0.36	0.16
AV-1 – Baseline	57	0.00	0.13
Lutein and Zeaxanthin (µg/ml)			
Baseline	57	0.19	0.09
AV-1	57	0.20	0.10
AV-1 – Baseline	57	0.00	0.06
Retinol (µg/ml)			
Baseline	57	0.61	0.15
AV-1	57	0.60	0.15
AV-1 – Baseline	57	-0.01	0.08

(continues)

Table 3.10 (continued)
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: August 31, 2001

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	55	137.73	32.63
AV-1	55	138.42	30.97
AV-1 - Baseline	54	0.72	18.41
Factor VII C (%)[1]			
Baseline	55	128.87	28.01
AV-1	55	126.93	26.60
AV-1 – Baseline	54	-2.04	14.64
Fibrinogen (mg/dl)			
Baseline	55	307.22	67.64
AV-1	55	312.07	76.37
AV-1 - Baseline	54	4.89	54.99
Hormones/Other			
Glucose (mg/dl)			
Baseline	57	105.42	27.56
AV-1	57	102.32	21.27
AV-1 - Baseline	57	-3.11	17.66
Insulin (µIU/ml)			
Baseline	54	13.23	7.71
AV-1	55	12.14	6.21
AV-1 - Baseline	52	-1.10	4.70

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.10 (continued)
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: August 31, 2001

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	56	172.61	78.71
AV-1	56	172.29	88.89
AV-1 – Baseline	55	-1.87	52.17
Total Cholesterol (mg/dl)			
Baseline	56	219.95	37.05
AV-1	56	211.45	37.03
AV-1 – Baseline	55	-7.84	23.63
LDL-C (mg/dl)			
Baseline	55	129.02	34.69
AV-1	53	123.87	33.30
AV-1 – Baseline	52	-5.42	20.42
HDL-C (mg/dl)			
Baseline	56	56.18	16.37
AV-1	56	55.61	15.35
AV-1 – Baseline	55	-0.07	7.51
HDL-2 (mg/dl)			
Baseline	54	17.91	8.37
AV-1	55	17.27	7.87
AV-1 – Baseline	52	0.27	4.41
HDL-3 (mg/dl)			
Baseline	55	38.89	8.48
AV-1	55	37.89	8.32
AV-1 – Baseline	53	-0.25	5.01
Lp(a) (mg/dl)			
Baseline	55	19.60	20.26
AV-1	55	20.22	19.98
AV-1 – Baseline	54	0.69	9.69

Table 3.10 (continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: August 31, 2001

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	173	0.10	0.10
AV-1	173	0.10	0.10
AV-1 – Baseline	173	0.00	0.10
Beta-Carotene (µg/ml)			
Baseline	173	0.44	0.41
AV-1	173	0.48	0.53
AV-1 – Baseline	173	0.05	0.40
Alpha-tocopherol (µg/ml)			
Baseline	173	19.19	9.77
AV-1	173	19.43	11.00
AV-1 – Baseline	173	0.24	6.70
Gamma-tocopherol (µg/ml)			
Baseline	173	1.69	1.19
AV-1	173	1.31	0.98
AV-1 – Baseline	173	-0.38	0.85
Beta-Cryptoxanthine (µg/ml)			
Baseline	173	0.18	0.17
AV-1	173	0.19	0.18
AV-1 - Baseline	173	0.01	0.14
Lycopene (µg/ml)			
Baseline	173	0.38	0.20
AV-1	173	0.36	0.19
AV-1 – Baseline	173	-0.02	0.18
Lutein and Zeaxanthin (µg/ml)			
Baseline	173	0.27	0.12
AV-1	173	0.28	0.12
AV-1 – Baseline	173	0.01	0.09
Retinol (µg/ml)			
Baseline	173	0.61	0.15
AV-1	173	0.62	0.15
AV-1 – Baseline	173	0.01	0.09

(continues)

Table 3.10 (continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: August 31, 2001

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	168	131.68	30.48
AV-1	165	130.78	29.41
AV-1 - Baseline	160	-0.90	20.53
Factor VII C (%)[1]			
Baseline	168	126.55	24.81
AV-1	165	125.51	25.75
AV-1 - Baseline	160	-1.48	17.75
Fibrinogen (mg/dl)			
Baseline	169	292.37	57.49
AV-1	165	285.18	57.29
AV-1 - Baseline	161	-6.73	53.28
Hormones/Other			
Glucose (mg/dl)			
Baseline	173	100.50	18.39
AV-1	173	100.83	23.90
AV-1 - Baseline	173	0.32	19.33
Insulin (µIU/ml)			
Baseline	169	10.28	5.76
AV-1	167	10.03	5.93
AV-1 - Baseline	163	-0.28	3.79

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.10 (continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: August 31, 2001

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	172	172.98	93.78
AV-1	173	173.16	94.65
AV-1 – Baseline	172	0.03	60.28
Total Cholesterol (mg/dl)			
Baseline	172	220.86	36.28
AV-1	173	213.32	33.53
AV-1 – Baseline	172	-7.55	24.43
LDL-C (mg/dl)			
Baseline	166	128.52	35.31
AV-1	167	120.96	30.35
AV-1 – Baseline	163	-8.54	25.14
HDL-C (mg/dl)			
Baseline	172	58.33	13.84
AV-1	173	59.65	13.97
AV-1 – Baseline	172	1.26	8.41
HDL-2 (mg/dl)			
Baseline	168	18.40	7.42
AV-1	171	19.38	7.30
AV-1 – Baseline	167	1.05	4.51
HDL-3 (mg/dl)			
Baseline	168	40.17	8.10
AV-1	171	40.36	8.29
AV-1 – Baseline	167	0.22	5.35
Lp(a) (mg/dl)			
Baseline	169	18.46	16.87
AV-1	172	16.12	13.83
AV-1 – Baseline	169	-2.16	12.82

Table 3.10 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: August 31, 2001

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	662	0.06	0.06
AV-1	661	0.07	0.07
AV-1 – Baseline	661	0.00	0.06
Beta-Carotene (µg/ml)			
Baseline	662	0.32	0.35
AV-1	661	0.32	0.30
AV-1 – Baseline	661	0.00	0.22
Alpha-tocopherol (µg/ml)			
Baseline	662	14.05	6.14
AV-1	661	14.53	6.09
AV-1 – Baseline	661	0.49	4.74
Gamma-tocopherol (µg/ml)			
Baseline	662	2.47	1.32
AV-1	661	2.26	1.32
AV-1 – Baseline	661	-0.20	0.91
Beta-Cryptoxanthine (µg/ml)			
Baseline	662	0.09	0.06
AV-1	661	0.09	0.06
AV-1 - Baseline	661	0.00	0.06
Lycopene (µg/ml)			
Baseline	662	0.39	0.21
AV-1	661	0.38	0.20
AV-1 – Baseline	661	-0.01	0.19
Lutein and Zeaxanthin (µg/ml)			
Baseline	662	0.24	0.11
AV-1	661	0.25	0.11
AV-1 – Baseline	661	0.01	0.08
Retinol (µg/ml)			
Baseline	662	0.55	0.15
AV-1	661	0.55	0.14
AV-1 – Baseline	661	0.01	0.09

(continues)

Table 3.10 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: August 31, 2001

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	641	114.56	27.16
AV-1	645	115.55	27.80
AV-1 - Baseline	625	1.01	20.67
Factor VII C (%)[1]			
Baseline	623	117.84	29.76
AV-1	633	115.92	26.50
AV-1 - Baseline	600	-2.17	20.92
Fibrinogen (mg/dl)			
Baseline	641	322.81	67.49
AV-1	646	320.36	67.18
AV-1 - Baseline	626	-3.27	49.35
Hormones/Other			
Glucose (mg/dl)			
Baseline	662	106.13	34.86
AV-1	658	106.85	38.21
AV-1 - Baseline	658	0.78	26.73
Insulin (μIU/ml)			
Baseline	654	13.90	10.08
AV-1	652	13.91	11.05
AV-1 - Baseline	645	-0.21	6.18

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.10 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: August 31, 2001

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	662	117.39	51.60
AV-1	661	117.93	47.71
AV-1 – Baseline	661	0.59	36.51
Total Cholesterol (mg/dl)			
Baseline	662	220.05	40.23
AV-1	661	216.80	41.72
AV-1 – Baseline	661	-3.28	26.06
LDL-C (mg/dl)			
Baseline	662	137.68	37.91
AV-1	660	133.37	39.46
AV-1 – Baseline	660	-4.39	24.32
HDL-C (mg/dl)			
Baseline	662	58.87	14.66
AV-1	661	59.90	14.99
AV-1 – Baseline	661	1.00	8.21
HDL-2 (mg/dl)			
Baseline	653	18.70	7.75
AV-1	654	19.51	8.67
AV-1 – Baseline	646	0.78	5.00
HDL-3 (mg/dl)			
Baseline	653	40.14	8.36
AV-1	654	40.33	7.97
AV-1 – Baseline	646	0.14	5.18
Lp(a) (mg/dl)			
Baseline	652	37.62	27.74
AV-1	657	37.83	28.27
AV-1 – Baseline	648	0.01	11.67

Table 3.10 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: August 31, 2001

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	259	0.09	0.10
AV-1	259	0.09	0.07
AV-1 – Baseline	259	0.00	0.10
Beta-Carotene (µg/ml)			
Baseline	259	0.30	0.42
AV-1	259	0.29	0.28
AV-1 – Baseline	259	-0.02	0.35
Alpha-tocopherol (µg/ml)			
Baseline	259	15.82	6.83
AV-1	259	17.07	7.72
AV-1 – Baseline	259	1.25	5.96
Gamma-tocopherol (µg/ml)			
Baseline	259	2.10	1.34
AV-1	259	1.84	1.33
AV-1 – Baseline	259	-0.26	0.94
Beta-Cryptoxanthine (µg/ml)			
Baseline	259	0.11	0.10
AV-1	259	0.11	0.10
AV-1 - Baseline	259	-0.01	0.09
Lycopene (µg/ml)			
Baseline	259	0.42	0.20
AV-1	259	0.40	0.18
AV-1 – Baseline	259	-0.02	0.16
Lutein and Zeaxanthin (µg/ml)			
Baseline	259	0.20	0.10
AV-1	259	0.20	0.10
AV-1 – Baseline	259	0.00	0.08
Retinol (µg/ml)			
Baseline	259	0.55	0.13
AV-1	259	0.56	0.13
AV-1 – Baseline	259	0.02	0.09

(continues)

Table 3.10 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: August 31, 2001

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	251	122.21	27.55
AV-1	247	124.00	28.68
AV-1 - Baseline	240	1.82	21.39
Factor VII C (%)[1]			
Baseline	244	121.06	27.22
AV-1	237	121.63	27.39
AV-1 - Baseline	228	0.28	21.13
Fibrinogen (mg/dl)			
Baseline	251	307.49	63.65
AV-1	246	307.33	67.35
AV-1 - Baseline	239	-0.21	55.94
Hormones/Other			
Glucose (mg/dl)			
Baseline	258	102.58	32.47
AV-1	258	104.22	34.85
AV-1 - Baseline	257	1.54	21.05
Insulin (µIU/ml)			
Baseline	253	13.73	8.87
AV-1	256	13.33	11.94
AV-1 - Baseline	250	-0.44	8.86

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.10 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: August 31, 2001

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	259	163.03	75.44
AV-1	259	165.46	77.05
AV-1 – Baseline	259	2.43	54.62
Total Cholesterol (mg/dl)			
Baseline	259	216.49	35.95
AV-1	259	212.15	35.84
AV-1 – Baseline	259	-4.34	25.16
LDL-C (mg/dl)			
Baseline	255	129.87	32.98
AV-1	254	124.56	33.61
AV-1 – Baseline	252	-5.70	22.53
HDL-C (mg/dl)			
Baseline	259	54.18	12.37
AV-1	259	55.54	12.60
AV-1 – Baseline	259	1.37	7.86
HDL-2 (mg/dl)			
Baseline	256	16.17	6.60
AV-1	256	16.93	6.85
AV-1 – Baseline	254	0.78	4.83
HDL-3 (mg/dl)			
Baseline	256	37.94	7.53
AV-1	256	38.61	7.57
AV-1 – Baseline	254	0.67	5.13
Lp(a) (mg/dl)			
Baseline	259	20.31	23.07
AV-1	255	19.15	20.12
AV-1 – Baseline	255	-0.98	7.89

Table 3.10 (continued)
Blood Specimen Analysis: White Women

Data as of: August 31, 2001

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	1198	0.08	0.08
AV-1	1201	0.08	0.07
AV-1 – Baseline	1196	0.00	0.06
Beta-Carotene (µg/ml)			
Baseline	1198	0.30	0.27
AV-1	1201	0.30	0.27
AV-1 – Baseline	1196	0.01	0.21
Alpha-tocopherol (µg/ml)			
Baseline	1198	16.36	6.87
AV-1	1201	17.16	7.43
AV-1 – Baseline	1196	0.78	5.45
Gamma-tocopherol (µg/ml)			
Baseline	1198	2.19	1.44
AV-1	1200	1.80	1.29
AV-1 – Baseline	1195	-0.39	0.93
Beta-Cryptoxanthine (µg/ml)			
Baseline	1198	0.08	0.06
AV-1	1200	0.09	0.07
AV-1 - Baseline	1195	0.00	0.05
Lycopene (µg/ml)			
Baseline	1198	0.42	0.19
AV-1	1201	0.41	0.19
AV-1 – Baseline	1196	-0.01	0.16
Lutein and Zeaxanthin (µg/ml)			
Baseline	1198	0.21	0.10
AV-1	1201	0.21	0.10
AV-1 – Baseline	1196	0.00	0.07
Retinol (µg/ml)			
Baseline	1198	0.63	0.15
AV-1	1201	0.63	0.15
AV-1 – Baseline	1196	0.00	0.10

(continues)

Table 3.10 (continued)
Blood Specimen Analysis: White Women

Data as of: August 31, 2001

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	1161	133.34	33.08
AV-1	1147	132.97	33.16
AV-1 - Baseline	1124	-0.48	22.68
Factor VII C (%)[1]			
Baseline	1143	131.53	30.76
AV-1	1139	128.86	30.66
AV-1 - Baseline	1098	-3.15	22.73
Fibrinogen (mg/dl)			
Baseline	1154	297.04	59.63
AV-1	1141	294.70	58.47
AV-1 - Baseline	1112	-2.20	49.35
Hormones/Other			
Glucose (mg/dl)			
Baseline	1199	99.28	25.24
AV-1	1197	97.56	23.91
AV-1 - Baseline	1193	-1.71	17.74
Insulin (μIU/ml)			
Baseline	1167	11.12	6.88
AV-1	1161	10.82	10.35
AV-1 - Baseline	1133	-0.30	8.97

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.10 (continued)
Blood Specimen Analysis: White Women

Data as of: August 31, 2001

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	1200	159.77	88.05
AV-1	1201	162.71	89.09
AV-1 – Baseline	1198	2.73	56.80
Total Cholesterol (mg/dl)			
Baseline	1200	225.30	37.65
AV-1	1201	218.26	37.10
AV-1 – Baseline	1198	-7.10	26.95
LDL-C (mg/dl)			
Baseline	1170	133.48	34.42
AV-1	1174	126.11	33.53
AV-1 – Baseline	1157	-7.18	23.80
HDL-C (mg/dl)			
Baseline	1194	60.04	15.97
AV-1	1199	59.63	15.50
AV-1 – Baseline	1191	-0.37	8.92
HDL-2 (mg/dl)			
Baseline	1158	18.88	8.37
AV-1	1171	19.07	8.44
AV-1 – Baseline	1134	0.19	4.99
HDL-3 (mg/dl)			
Baseline	1159	41.32	9.21
AV-1	1172	40.63	8.71
AV-1 – Baseline	1136	-0.70	5.62
Lp(a) (mg/dl)			
Baseline	1182	24.79	26.44
AV-1	1181	24.21	26.13
AV-1 – Baseline	1164	-0.59	9.91

Table 3.10 (continued)
Blood Specimen Analysis: Other/Unspecified Women

Data as of: August 31, 2001

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	47	0.08	0.08
AV-1	47	0.08	0.08
AV-1 – Baseline	47	0.00	0.06
Beta-Carotene (µg/ml)			
Baseline	47	0.27	0.22
AV-1	47	0.28	0.21
AV-1 – Baseline	47	0.01	0.13
Alpha-tocopherol (µg/ml)			
Baseline	47	17.39	9.53
AV-1	47	17.11	9.50
AV-1 – Baseline	47	-0.27	6.60
Gamma-tocopherol (µg/ml)			
Baseline	47	2.14	1.17
AV-1	47	2.01	1.06
AV-1 – Baseline	47	-0.13	0.76
Beta-Cryptoxanthine (µg/ml)			
Baseline	47	0.11	0.12
AV-1	47	0.10	0.06
AV-1 - Baseline	47	-0.01	0.08
Lycopene (µg/ml)			
Baseline	47	0.41	0.19
AV-1	47	0.40	0.20
AV-1 – Baseline	47	0.00	0.18
Lutein and Zeaxanthin (µg/ml)			
Baseline	47	0.22	0.12
AV-1	47	0.23	0.16
AV-1 – Baseline	47	0.01	0.10
Retinol (µg/ml)			
Baseline	47	0.58	0.18
AV-1	47	0.59	0.15
AV-1 – Baseline	47	0.00	0.11

(continues)

Table 3.10 (continued)
Blood Specimen Analysis: Other/Unspecified Women

Data as of: August 31, 2001

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	47	122.11	28.69
AV-1	45	117.58	27.66
AV-1 - Baseline	45	-2.40	24.80
Factor VII C (%)[1]			
Baseline	47	123.79	30.04
AV-1	44	120.57	24.77
AV-1 - Baseline	44	0.16	22.00
Fibrinogen (mg/dl)			
Baseline	47	308.19	66.86
AV-1	45	299.29	64.83
AV-1 - Baseline	45	-8.87	40.15
Hormones/Other			
Glucose (mg/dl)			
Baseline	47	100.15	25.64
AV-1	47	100.81	25.69
AV-1 - Baseline	47	0.66	11.98
Insulin (μIU/ml)			
Baseline	47	10.28	6.10
AV-1	47	10.76	5.66
AV-1 - Baseline	47	0.48	3.31

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.10 (continued)
Blood Specimen Analysis: Other/Unspecified Women

Data as of: August 31, 2001

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	46	162.33	103.41
AV-1	46	158.20	77.22
AV-1 – Baseline	46	-4.13	60.55
Total Cholesterol (mg/dl)			
Baseline	46	231.04	37.16
AV-1	46	228.89	35.03
AV-1 – Baseline	46	-2.15	26.65
LDL-C (mg/dl)			
Baseline	44	139.02	35.27
AV-1	46	136.24	34.66
AV-1 – Baseline	44	-1.02	24.64
HDL-C (mg/dl)			
Baseline	46	60.04	17.19
AV-1	46	60.93	15.78
AV-1 – Baseline	46	0.89	9.97
HDL-2 (mg/dl)			
Baseline	46	20.17	11.00
AV-1	46	20.43	10.39
AV-1 – Baseline	46	0.26	6.47
HDL-3 (mg/dl)			
Baseline	46	39.87	7.61
AV-1	46	40.50	7.06
AV-1 – Baseline	46	0.63	5.98
Lp(a) (mg/dl)			
Baseline	47	24.60	30.87
AV-1	45	21.38	20.98
AV-1 – Baseline	45	-0.62	9.18

Table 3.11
Bone Mineral Density[1] Analysis: DM Participants

Data as of: August 31, 2001

	N	Mean	S.D.
Whole Body Scan			
Baseline	3619	1.03	0.11
AV1	3274	1.03	0.11
AV3	3096	1.04	0.11
AV6	1393	1.06	0.13
AV1 % Change from baseline BMD[2]	3246	0.18	2.49
AV3 % Change from baseline BMD[3]	3070	1.29	3.60
AV6 % Change from baseline BMD[4]	1376	2.56	5.23
Spine Scan			
Baseline	3532	0.99	0.17
AV1	3199	1.00	0.17
AV3	3025	1.01	0.17
AV6	1373	1.01	0.17
AV1 % Change from baseline BMD[2]	3177	0.73	3.83
AV3 % Change from baseline BMD[3]	3004	2.13	5.23
AV6 % Change from baseline BMD[4]	1362	3.31	6.72
Hip Scan			
Baseline	3618	0.87	0.14
AV1	3273	0.87	0.14
AV3	3095	0.88	0.14
AV6	1409	0.88	0.14
AV1 % Change from baseline BMD[2]	3252	-0.04	2.76
AV3 % Change from baseline BMD[3]	3068	0.99	4.16
AV6 % Change from baseline BMD[4]	1395	1.07	5.07

[1] Measured in (g/cm^2).
[2] AV1 % Change from baseline BMD is defined as ((AV1-Baseline)/Baseline)x100.
[3] AV3 % Change from baseline BMD is defined as ((AV3-Baseline)/Baseline)x100.
[4] AV6 % Change from baseline BMD is defined as ((AV6-Baseline)/Baseline)x100.

Table 3.12
Bone Mineral Density[1] Analysis: DM Participants by Race/Ethnicicty

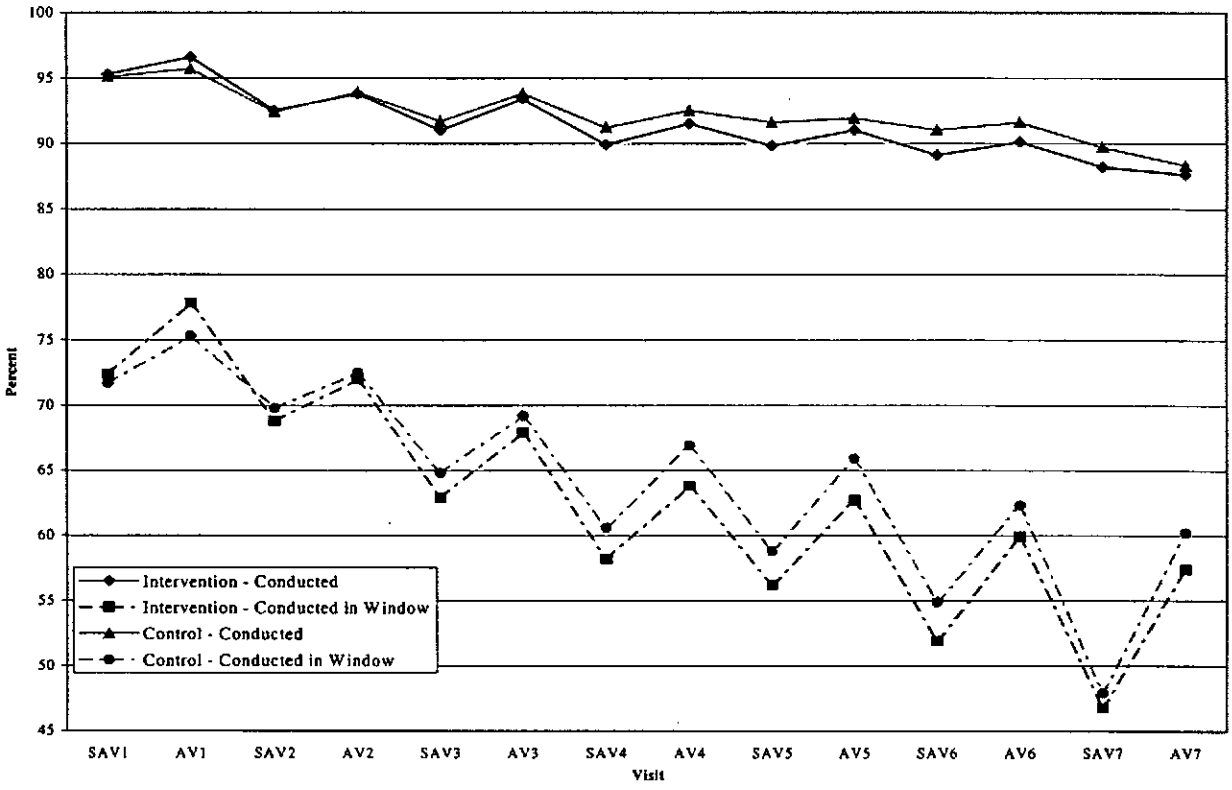
Data as of: August 31, 2001

	Black/African American			Hispanic/Latino			White		
	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan									
Baseline	582	1.07	0.11	195	1.05	0.11	2785	1.01	0.11
AV1	512	1.09	0.11	152	1.05	0.11	2567	1.01	0.10
AV3	496	1.10	0.12	152	1.05	0.12	2406	1.03	0.11
AV6	150	1.10	0.11	51	1.10	0.14	1166	1.05	0.12
AV1 % Change from baseline BMD[2]	506	0.99	2.96	151	-0.33	2.24	2547	0.06	2.37
AV3 % Change from baseline BMD[3]	491	2.03	2.95	151	0.65	4.45	2387	1.19	3.65
AV6 % Change from baseline BMD[4]	149	0.31	3.46	51	4.10	6.31	1151	2.78	5.29
Spine Scan									
Baseline	577	1.07	0.18	190	0.98	0.16	2708	0.98	0.16
AV1	507	1.08	0.18	148	0.98	0.16	2501	0.98	0.16
AV3	492	1.09	0.19	149	0.96	0.15	2342	1.00	0.17
AV6	153	1.12	0.19	48	0.96	0.15	1146	1.00	0.17
AV1 % Change from baseline BMD[2]	502	0.81	4.31	147	0.15	4.36	2486	0.75	3.67
AV3 % Change from baseline BMD[3]	488	2.11	5.26	148	-0.11	6.24	2327	2.30	5.13
AV6 % Change from baseline BMD[4]	152	2.09	7.11	48	1.23	6.74	1137	3.58	6.65
Hip Scan									
Baseline	584	0.97	0.15	195	0.88	0.14	2782	0.85	0.13
AV1	514	0.98	0.15	152	0.88	0.14	2564	0.85	0.13
AV3	497	0.99	0.15	152	0.88	0.15	2404	0.86	0.13
AV6	155	0.99	0.15	51	0.88	0.15	1177	0.87	0.13
AV1 % Change from baseline BMD[2]	510	0.85	2.87	151	-0.62	2.94	2549	-0.18	2.67
AV3 % Change from baseline BMD[3]	493	1.41	3.82	150	0.80	5.76	2384	0.91	4.08
AV6 % Change from baseline BMD[4]	154	-1.18	5.07	50	1.36	5.06	1166	1.35	4.98

[1] Measured in (g/cm^2).
[2] AV1 % Change from baseline BMD is defined as ((AV1-Baseline)/Baseline)x100.
[3] AV3 % Change from baseline BMD is defined as ((AV3-Baseline)/Baseline)x100.
[4] AV6 % Change from baseline BMD is defined as ((AV6-Baseline)/Baseline)x100.

Table 3.13
Adherence to Follow-up Contacts

Data as of: August 31, 2001



Contact		Due N	Conducted N	Conducted %	Conducted in window N	Conducted in window %
Semi-Annual Contact 1	Intervention	19542	18630	95.3	14153	72.4
	Control	29294	27867	95.1	20990	71.7
Annual Visit 1	Intervention	19542	18887	96.6	15198	77.8
	Control	29294	28021	95.7	22054	75.3
Semi-Annual Contact 2	Intervention	19542	18067	92.5	13450	68.8
	Control	29294	27082	92.4	20435	69.8
Annual Visit 2	Intervention	19542	18339	93.8	14066	72.0
	Control	29294	27508	93.9	21242	72.5
Semi-Annual Contact 3	Intervention	19542	17777	91.0	12295	62.9
	Control	29294	26857	91.7	18980	64.8
Annual Visit 3	Intervention	19539	18247	93.4	13262	67.9
	Control	29289	27487	93.8	20255	69.2
Semi-Annual Contact 4	Intervention	18100	16276	89.9	10538	58.2
	Control	27154	24757	91.2	16458	60.6
Annual Visit 4	Intervention	15679	14342	91.5	10011	63.8
	Control	23494	21733	92.5	15721	66.9
Semi-Annual Contact 5	Intervention	12709	11416	89.8	7144	56.2
	Control	19045	17439	91.6	11190	58.8
Annual Visit 5	Intervention	9530	8673	91.0	5976	62.7
	Control	14314	13153	91.9	9427	65.9
Semi-Annual Visit 6	Intervention	6659	5931	89.1	3457	51.9
	Control	9951	9053	91.0	5461	54.9
Annual Visit 6	Intervention	4372	3939	90.1	2618	59.9
	Control	6531	5980	91.6	4067	62.3
Semi-Annual Visit 7	Intervention	2690	2373	88.2	1260	46.8
	Control	4017	3605	89.7	1926	47.9
Annual Visit 7	Intervention	1322	1158	87.6	759	57.4
	Control	1998	1765	88.3	1203	60.2

Table 3.14
Lost-to-Follow-up and Vital Status: DM Participants

Data as of: August 31, 2001

	DM Participants (N = 48,836)	
	N	%
Vital Status/Participation		
Deceased	959	2.0
Alive: Current Participation[1]	45144	92.4
Alive: Recent Participation[2]	1037	2.1
Alive: Past/Unknown Participation[3]	54	0.1
Stopped Follow-Up[4]	936	1.9
Lost to Follow-Up[5]	706	1.4

[1] Participants who have filled in a Form 33 within the last 9 months.
[2] Participants who last filled in a Form 33 between 9 and 18 months ago.
[3] Participiants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.
[5] Participants not in any of the above categories.

Table 3.15
Locally Verified Outcomes (Annualized Percentages) by Age for Dietary Modification

Data as of: August 31, 2001

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	48836	6961	11042	22715	8118
Mean follow-up (months)	56.3	62.6	58.5	54.2	53.8
Cancer					
Breast cancer[1]	1071 (0.47%)	117 (0.32%)	248 (0.46%)	514 (0.50%)	192 (0.53%)
Invasive breast cancer	849 (0.37%)	82 (0.23%)	199 (0.37%)	413 (0.40%)	155 (0.43%)
Non-invasive breast cancer	233 (0.10%)	35 (0.10%)	53 (0.10%)	106 (0.10%)	39 (0.11%)
Ovary cancer	105 (0.05%)	17 (0.05%)	20 (0.04%)	43 (0.04%)	25 (0.07%)
Endometrial cancer[2]	145 (0.11%)	20 (0.10%)	35 (0.11%)	61 (0.11%)	29 (0.15%)
Colorectal cancer	272 (0.12%)	18 (0.05%)	46 (0.09%)	137 (0.13%)	71 (0.19%)
Other cancer[3]	1027 (0.45%)	90 (0.25%)	169 (0.31%)	513 (0.50%)	255 (0.70%)
Total cancer	2556 (1.12%)	256 (0.71%)	502 (0.93%)	1240 (1.21%)	558 (1.53%)
Cardiovascular					
CHD[4]	637 (0.28%)	39 (0.11%)	75 (0.14%)	304 (0.30%)	219 (0.60%)
CHD death[5]	122 (0.05%)	7 (0.02%)	12 (0.02%)	55 (0.05%)	48 (0.13%)
Total MI[6]	557 (0.24%)	33 (0.09%)	67 (0.12%)	266 (0.26%)	191 (0.52%)
Clinical MI	535 (0.23%)	28 (0.08%)	66 (0.12%)	255 (0.25%)	186 (0.51%)
Evolving Q-wave MI[7]	34 (0.01%)	6 (0.02%)	2 (<0.01%	17 (0.02%)	9 (0.02%)
Possible evolving Q-wave MI[7]	122 (0.05%)	12 (0.03%)	23 (0.04%)	55 (0.05%)	32 (0.09%)
Angina	936 (0.41%)	55 (0.15%)	121 (0.22%)	481 (0.47%)	279 (0.77%)
CABG/PTCA	852 (0.37%)	40 (0.11%)	113 (0.21%)	433 (0.42%)	266 (0.73%)
Carotid artery disease	166 (0.07%)	6 (0.02%)	20 (0.04%)	77 (0.08%)	63 (0.17%)
Congestive heart failure	479 (0.21%)	25 (0.07%)	50 (0.09%)	213 (0.21%)	191 (0.52%)
Stroke	490 (0.21%)	24 (0.07%)	44 (0.08%)	222 (0.22%)	200 (0.55%)
PVD	117 (0.05%)	4 (0.01%)	14 (0.03%)	55 (0.05%)	44 (0.12%)
CHD[4]/Possible evolving Q-wave MI	738 (0.32%)	51 (0.14%)	93 (0.17%)	347 (0.34%)	247 (0.68%)
Coronary disease[8]	1926 (0.84%)	119 (0.33%)	243 (0.45%)	956 (0.93%)	608 (1.67%)
Total cardiovascular disease	2548 (1.11%)	147 (0.40%)	305 (0.57%)	1252 (1.22%)	844 (2.32%)
Fractures					
Hip fracture	192 (0.08%)	7 (0.02%)	17 (0.03%)	79 (0.08%)	89 (0.24%)
Vertebral fracture	225 (0.10%)	10 (0.03%)	23 (0.04%)	95 (0.09%)	97 (0.27%)
Other fracture[3]	2969 (1.30%)	369 (1.02%)	591 (1.10%)	1405 (1.37%)	604 (1.66%)
Total fracture	3288 (1.43%)	383 (1.06%)	626 (1.16%)	1538 (1.50%)	741 (2.03%)
Deaths					
Cardiovascular deaths	264 (0.12%)	12 (0.03%)	21 (0.04%)	122 (0.12%)	109 (0.30%)
Cancer deaths	448 (0.20%)	27 (0.07%)	57 (0.11%)	226 (0.22%)	138 (0.38%)
Deaths: other known cause	125 (0.05%)	8 (0.02%)	17 (0.03%)	49 (0.05%)	51 (0.14%)
Deaths: unknown cause	122 (0.05%)	9 (0.02%)	11 (0.02%)	61 (0.06%)	41 (0.11%)
Deaths: not yet adjudicated	76 (0.03%)	6 (0.02%)	4 (0.01%)	39 (0.04%)	27 (0.07%)
Total death	959 (0.42%)	56 (0.15%)	106 (0.20%)	458 (0.45%)	339 (0.93%)

[1] Excludes four cases with borderline malignancy.
[2] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[3] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.
[4] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death. This definition has changed slightly from the February 2001 report.
[5] "CHD death" includes definite and possible CHD death. This definition has changed slightly from the February 2001 report.
[6] "Total MI" includes clinical MI and evolving Q-wave MI.
[7] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[8] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

Table 3.15 (continued)
Locally Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Dietary Modification

Data as of: August 31, 2001

Outcome	Race/Ethnicity: American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Other/ Unspecified
Number randomized	202	1105	5262	1845	39763	659
Mean follow-up (months)	55.4	52.6	54.9	52.3	56.9	52.0
Cancer						
Breast cancer[1]	2 (0.21%)	22 (0.45%)	67 (0.28%)	24 (0.30%)	947 (0.50%)	9 (0.32%)
Invasive breast cancer	2 (0.21%)	19 (0.39%)	52 (0.22%)	18 (0.22%)	753 (0.40%)	5 (0.18%)
Non-invasive breast cancer	0 (0.00%)	3 (0.06%)	17 (0.07%)	6 (0.07%)	203 (0.11%)	4 (0.14%)
Ovary cancer	2 (0.21%)	1 (0.02%)	10 (0.04%)	2 (0.02%)	88 (0.05%)	2 (0.07%)
Endometrial cancer[2]	0 (0.00%)	1 (0.03%)	11 (0.10%)	7 (0.16%)	124 (0.11%)	2 (0.12%)
Colorectal cancer	2 (0.21%)	5 (0.10%)	35 (0.15%)	13 (0.16%)	213 (0.11%)	4 (0.14%)
Other cancer[3]	2 (0.21%)	13 (0.27%)	76 (0.32%)	23 (0.29%)	901 (0.48%)	12 (0.42%)
Total cancer	8 (0.86%)	42 (0.87%)	195 (0.81%)	65 (0.81%)	2221 (1.18%)	25 (0.88%)
Cardiovascular						
CHD[4]	1 (0.11%)	4 (0.08%)	61 (0.25%)	10 (0.12%)	556 (0.29%)	5 (0.18%)
CHD death[5]	0 (0.00%)	0 (0.00%)	17 (0.07%)	1 (0.01%)	102 (0.05%)	2 (0.07%)
Total MI[6]	1 (0.11%)	4 (0.08%)	52 (0.22%)	10 (0.12%)	485 (0.26%)	5 (0.18%)
Clinical MI	1 (0.11%)	4 (0.08%)	48 (0.20%)	10 (0.12%)	468 (0.25%)	4 (0.14%)
Evolving Q-wave MI[7]	0 (0.00%)	0 (0.00%)	4 (0.02%)	0 (0.00%)	29 (0.02%)	1 (0.04%)
Possible evolving Q-wave MI[7]	1 (0.11%)	3 (0.06%)	14 (0.06%)	2 (0.02%)	101 (0.05%)	1 (0.04%)
Angina	2 (0.21%)	12 (0.25%)	125 (0.52%)	25 (0.31%)	761 (0.40%)	11 (0.39%)
CABG/PTCA	1 (0.11%)	7 (0.14%)	75 (0.31%)	18 (0.22%)	746 (0.40%)	5 (0.18%)
Carotid artery disease	2 (0.21%)	3 (0.06%)	15 (0.06%)	1 (0.01%)	143 (0.08%)	2 (0.07%)
Congestive heart failure	0 (0.00%)	1 (0.02%)	82 (0.34%)	11 (0.14%)	378 (0.20%)	7 (0.25%)
Stroke	3 (0.32%)	13 (0.27%)	60 (0.25%)	10 (0.12%)	396 (0.21%)	8 (0.28%)
PVD	1 (0.11%)	0 (0.00%)	25 (0.10%)	1 (0.01%)	88 (0.05%)	2 (0.07%)
CHD[4]/Possible evolving Q-wave MI	2 (0.21%)	7 (0.14%)	74 (0.31%)	12 (0.15%)	637 (0.34%)	6 (0.21%)
Coronary disease[8]	4 (0.43%)	19 (0.39%)	250 (1.04%)	47 (0.58%)	1584 (0.84%)	22 (0.77%)
Total cardiovascular disease	10 (1.07%)	33 (0.68%)	322 (1.34%)	58 (0.72%)	2094 (1.11%)	31 (1.09%)
Fractures						
Hip fracture	0 (0.00%)	0 (0.00%)	6 (0.02%)	1 (0.01%)	183 (0.10%)	2 (0.07%)
Vertebral fracture	0 (0.00%)	5 (0.10%)	1 (<0.01%	5 (0.06%)	212 (0.11%)	2 (0.07%)
Other fracture[3]	11 (1.18%)	46 (0.95%)	167 (0.69%)	69 (0.86%)	2645 (1.40%)	31 (1.09%)
Total fracture	11 (1.18%)	51 (1.05%)	173 (0.72%)	73 (0.91%)	2945 (1.56%)	35 (1.23%)
Deaths						
Cardiovascular deaths	1 (0.11%)	3 (0.06%)	37 (0.15%)	3 (0.04%)	216 (0.11%)	4 (0.14%)
Cancer deaths	1 (0.11%)	3 (0.06%)	39 (0.16%)	9 (0.11%)	389 (0.21%)	7 (0.25%)
Deaths: other known cause	4 (0.43%)	0 (0.00%)	20 (0.08%)	2 (0.02%)	97 (0.05%)	2 (0.07%)
Deaths: unknown cause	0 (0.00%)	5 (0.10%)	12 (0.05%)	6 (0.07%)	99 (0.05%)	0 (0.00%)
Deaths: not yet adjudicated	0 (0.00%)	5 (0.10%)	6 (0.02%)	5 (0.06%)	60 (0.03%)	0 (0.00%)
Total death	6 (0.64%)	11 (0.23%)	108 (0.45%)	20 (0.25%)	801 (0.42%)	13 (0.46%)

[1] Excludes four cases with borderline malignancy.
[2] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[3] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.
[4] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death. This definition has changed slightly from the February 2001 report.
[5] "CHD death" includes definite and possible CHD death. This definition has changed slightly from the February 2001 report.
[6] "Total MI" includes clinical MI and evolving Q-wave MI.
[7] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[8] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

Table 3.16
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for DM Participants who did not report a prevalent condition at baseline

Data as of: August 31, 2001

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	48836	6961	11042	22715	8118
Mean follow-up (months)	56.3	62.6	58.5	54.2	53.8
Hospitalizations					
Ever	16273 (7.10%)	1739 (4.79%)	3063 (5.69%)	7844 (7.64%)	3627 (9.96%)
Two or more	6863 (2.99%)	636 (1.75%)	1160 (2.15%)	3269 (3.19%)	1798 (4.94%)
Other					
DVT[1]	292 (0.13%)	20 (0.06%)	46 (0.09%)	137 (0.14%)	89 (0.26%)
Pulmonary embolism	172 (0.08%)	10 (0.03%)	29 (0.05%)	86 (0.08%)	47 (0.13%)
Diabetes (treated)	1967 (0.90%)	277 (0.78%)	449 (0.86%)	906 (0.93%)	335 (0.97%)
Gallbladder disease[2]	2321 (1.21%)	357 (1.10%)	543 (1.18%)	1083 (1.29%)	338 (1.15%)
Hysterectomy	947 (0.73%)	143 (0.70%)	218 (0.67%)	435 (0.76%)	151 (0.76%)
Glaucoma	2855 (1.29%)	286 (0.80%)	547 (1.04%)	1408 (1.43%)	614 (1.82%)
Osteoporosis	6072 (2.81%)	604 (1.70%)	1057 (2.03%)	3054 (3.18%)	1357 (4.17%)
Osteoarthritis[3]	5876 (4.23%)	818 (3.11%)	1324 (3.68%)	2748 (4.68%)	986 (5.49%)
Rheumatoid arthritis	1706 (0.77%)	242 (0.68%)	389 (0.74%)	774 (0.79%)	301 (0.87%)
Intestinal polyps	4025 (1.89%)	496 (1.41%)	882 (1.72%)	1981 (2.10%)	666 (2.05%)
Lupus	279 (0.12%)	47 (0.13%)	61 (0.11%)	136 (0.13%)	35 (0.10%)
Kidney stones[3]	647 (0.38%)	87 (0.34%)	146 (0.37%)	317 (0.40%)	97 (0.35%)
Cataracts[3]	8600 (5.51%)	479 (1.85%)	1332 (3.39%)	4812 (6.76%)	1977 (10.03%)
Pills for hypertension	7153 (4.46%)	972 (3.32%)	1612 (3.96%)	3312 (4.81%)	1257 (5.82%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Other/ Unspecified
Number randomized	202	1105	5262	1845	39763	659
Mean follow-up (months)	55.4	52.6	54.9	52.3	56.9	52.0
Hospitalizations						
Ever	59 (6.33%)	215 (4.44%)	1732 (7.20%)	501 (6.24%)	13573 (7.20%)	193 (6.76%)
Two or more	34 (3.65%)	71 (1.47%)	749 (3.11%)	193 (2.40%)	5739 (3.04%)	77 (2.70%)
Other						
DVT[1]	0 (0.00%)	0 (0.00%)	25 (0.11%)	4 (0.05%)	260 (0.14%)	3 (0.11%)
Pulmonary embolism	1 (0.11%)	1 (0.02%)	13 (0.05%)	2 (0.02%)	151 (0.08%)	4 (0.14%)
Diabetes (treated)	13 (1.50%)	56 (1.23%)	391 (1.83%)	108 (1.43%)	1372 (0.75%)	27 (1.00%)
Gallbladder disease[2]	10 (1.51%)	37 (0.85%)	187 (0.87%)	87 (1.43%)	1969 (1.26%)	31 (1.27%)
Hysterectomy	3 (0.68%)	18 (0.59%)	58 (0.54%)	26 (0.61%)	838 (0.76%)	4 (0.25%)
Glaucoma	13 (1.46%)	57 (1.22%)	407 (1.81%)	97 (1.25%)	2249 (1.23%)	32 (1.19%)
Osteoporosis	26 (2.93%)	132 (2.88%)	312 (1.35%)	214 (2.86%)	5305 (2.99%)	83 (3.14%)
Osteoarthritis[3]	27 (5.14%)	126 (3.65%)	604 (4.25%)	250 (4.66%)	4792 (4.22%)	77 (4.46%)
Rheumatoid arthritis	14 (1.68%)	30 (0.64%)	309 (1.37%)	140 (1.83%)	1184 (0.65%)	29 (1.07%)
Intestinal polyps	24 (2.80%)	84 (1.89%)	428 (1.90%)	131 (1.71%)	3295 (1.88%)	63 (2.40%)
Lupus	3 (0.33%)	3 (0.06%)	39 (0.16%)	7 (0.09%)	224 (0.12%)	3 (0.11%)
Kidney stones[3]	4 (0.60%)	13 (0.35%)	62 (0.35%)	34 (0.55%)	524 (0.37%)	10 (0.46%)
Cataracts[3]	37 (6.02%)	174 (5.15%)	818 (4.97%)	288 (4.91%)	7158 (5.60%)	125 (6.34%)
Pills for hypertension	31 (5.17%)	156 (4.80%)	819 (6.78%)	295 (4.93%)	5767 (4.22%)	85 (4.40%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 3.17
Sensitivity of DM Study Power to Adherence Assumptions

Outcome	Year	Intervention Effect[1] (%)	Percentage of Cases[1]		Power (%)	
			Control	Intervention	Design[2]	Revised[3]
Breast Cancer						
	2001	11	1.98	1.86	28	18
		12	1.99	1.85	35	22
		14	1.99	1.83	44	27
	2004	11	2.86	2.61	63	46
		12	2.86	2.57	75	56
		14	2.86	2.54	86	67
Colorectal Cancer						
	2001	18	1.08	0.97	37	18
		20	1.08	0.96	45	21
		22	1.09	0.95	52	25
	2004	18	1.64	1.40	83	51
		20	1.63	1.37	90	60
		22	1.63	1.24	95	69

[1] Intervention Effects and Percentage of Cases are shown for original Design assumptions. The other adherence patterns would produce greater incidence rates in Intervention women and a corresponding reduction in the estimated treatment effect.
[2] C-I % Energy from fat: 13% at AV-1, 11% at year 10
[3] C-I % Energy from fat: 11% at AV-1, 9% at year 10. 8.5 follow-up years, using observed control rates for years 1-5 and adjustment toward design rates thereafter.

4. CaD Component

4.1 Recruitment

Table 4.1 presents the final sample size for number of women randomized in the Calcium and Vitamin D component of the WHI Clinical Trial. A total of 36,282 women have been randomized which is 80.6% of the overall goal of 45,000. The age distribution of the CaD trial participants is somewhat younger than anticipated in the design assumptions for the trial. Seventeen percent of women randomized are aged 70-79 years compared with the design assumption of 25%.

4.2 Adherence

Table 4.2 presents rates of follow-up, stopping intervention and pill collection, and adherence to pill taking by visit schedule for all CaD participants. The adherence summary for all CaD participants, defined as those women known to be consuming 80% or more of the prescribed dose, has remained steady since the last report (see *Figure 4.1*) and is now 57%-63% (adherence summary was 58%-63% in the last progress report). At AV-3, which is nearly complete, 97% of visits due have been conducted, 94% of women continue to take CaD study medication, and 91% completed the pill collection procedure. The adherence summary remains low primarily because about 20-30% of women on study medication take less than 80% of their CaD pills.

Table 4.3 summarizes interval and cumulative drop-out rates in comparison to the original design assumptions. The original power calculations for CaD assumed a 6% drop-out rate in year 1 and a 3% per year drop-out rate thereafter. An independent lost-to-follow-up rate of 3% per year was also incorporated, resulting in approximately 8.8% stopping intervention in year 1 and 5.9% in subsequent years. Our current data suggest the drop-out rates are somewhat higher than projected at AV-2 and AV-3, and then lower (absolute difference of 1-3%) than projected at AV-4 – AV-7. By AV-6, the observed cumulative rate of stopping, death, or loss-to-follow-up is 28.9% which is 0.4% lower than the design-projected cumulative drop-out rate of 28.5%.

Figure 4.1 shows the CaD adherence summary over six month periods from the present period ending August 31, 2001 to September 1997-February 1998. The graph shows that CaD adherence has improved over this 3-4 year period. In the most recent interval, small improvement was noted at AV-4 and AV-5.

Table 4.4 summarizes the frequency of reported reasons for stopping CaD. The majority of women stopping study supplements do so of their own accord. Only 8.2% have indicated that they were advised by their physician to discontinue these supplements. 600 women (7.5%) reported health problems or diseases, 2309 women (29.0%) reported symptoms not known to be related to the intervention, and 478 women (6.0%) reported that the study conflicts with other health issues. "Other pill issues" was the most frequently reported intervention-related reason (11.4%) followed by not liking the randomized nature of the intervention (4.3%). Miscellaneous reasons grouped together as "other reasons not listed above" were reported by 23.2% of women. Four common reasons for stopping CaD are shown first by age, and then by race/ethnicity, in *Table 4.5*. No strong associations by age are present, though "being advised by one's health care provider not to participate" and "study conflicts with other health issues"

were slightly more common among older women. These reasons were reported with similar frequency by women in the various race/ethnicity subgroups.

We also monitor the number of women who have begun alternative anti-osteoporosis therapies within the CaD trial. As of August 31, 2001, 1,618 (4.5%) women were taking alendronate, 229 (0.6%) were taking calcitonin, and 513 (1.4%) were taking raloxifene.

4.3 Bone Mineral Density

Table 4.6 presents the mean bone mineral density levels at AV-1 and AV-3 and percent change in BMD during this interval among women randomized at the three BMD measurement sites (Pittsburgh, Arizona, Birmingham). At the three skeletal sites examined (hip, spine, and whole body), BMD has increased between AV-1 and AV-3 from 1.3-1.6%, with the greatest change occurring at the spine. The percent changes between AV-6 and AV-1 were approximately 1.5-2 times as large as those observed at AV-3 ranging from 1.8% at the hip to 3.2% at the whole body. *Table 4.7* presents the mean bone mineral density levels and percent change according to race/ethnicity. The number of Black/African American and Hispanic/Latino women who have data available at AV-6 is too small to yield reliable estimates. However, at AV-3 the rates of change relative to AV-1 were generally in the range of 1-2% gains for all skeletal sites.

4.4 Vital Status

Table 4.8 presents data on the vital status and the participation status of participants in the CaD trial. A detailed description of CCC and clinic activities to actively locate participants who do not complete their periodic visits is given in *Section 6 – Outcomes*. For operational purposes, we define CT participants to have an "unknown" participation status if there is no outcomes information from the participant for 18 months and no other contacts for 6 months. Currently, 1.7% of the participants are lost-to-follow-up or have stopped follow-up, and 1.5% of the participants are known to be deceased. Virtually all of the remaining participants have completed a *Form 33 – Medical History Update* in the last 18 months. The design assumed that 3% per year would be lost-to-follow-up or death. Currently, the average follow-up for CaD participants is about 3.6 years, suggesting that approximately 10.4% could be expected to be dead or lost-to-follow-up. Our overall rates compare favorably to design assumptions.

4.5 Outcomes

Table 4.9 contains counts of the number of locally verified major WHI outcomes for CaD participants. In this table only outcomes that took place after randomization in the CaD trial are included. Approximately 5% of the self-reported outcomes have not yet been verified, so the numbers in this table should thus be seen as a lower bound to the actual number of outcomes that have taken place. Currently, with 123 cases of hip fracture locally verified, we have observed only about 35% of the number of hip fractures that were projected by the assumptions underlying the power calculations. The number of observed colorectal cancer cases (153 cases) is approximately 75%, the number of invasive breast cancer cases (488 cases) is approximately 105%, and the number of CHD cases is about 65% of what was expected (390 cases).

Table 4.10 contains counts of the number of self-reports for some outcomes that are not locally verified in WHI. As most of the self-reported outcomes are somewhat over reported (see

Section 6.3 – Outcomes Data Quality), the number in this table should be taken as an upper bound to the number of events that have occurred in CaD participants.

4.6 Power Considerations

Power calculations in this report have been revised to reflect the actual sample size recruited into CaD and the observed incidence rates in the control group for years 1-4 with projections based on observed data thereafter. We have calculated the power for CaD using the type of adherence model employed for the DM component. This approach incorporates total calcium intake from diet and supplements. To make within-model comparisons, we determined the calcium intake assumptions that would reproduce the original power calculations based on a model that dichotomized adherence to pills, holding constant all other parameters (e.g., treatment effect, lag time, control group incidence rates, and average follow-up time). Average total calcium consumption (in mg) of 920, 950, 1000 at baseline, year 1 and year 9, respectively in controls and similarly 1920, 1850, 1800 in the intervention arm produces powers within 1%-2% of the protocol-specified values with n=45,000 for all outcomes of interest. The value of 920 mg/day in controls at baseline was determined from the median total calcium intake in the CaD participants at AV-1 who are also DM participants, and who therefore provide FFQ data.

Using a sample size of 36,282, an adherence pattern suggested by the current data, and revised incidence rates reflecting the low early rates of hip fracture as described above, *Table 4.11* shows the power for hip fractures, other fractures and colorectal cancer. Note that power for hip fracture and colorectal cancer is low (33%) in year 2001 but improves substantially (to 67%) by year 2004. Power for combined fractures remains high under the examined scenarios with current adherence patterns assumed.

4.7 Issues

During this period of follow-up, the focus remained primarily on maximizing adherence and retention in all components of the WHI Clinical Trial. Work continues on identifying and implementing strategies to improve adherence to CaD study medication. As an example, static cling decal pill reminders were delivered to clinical centers in mid-October 2001 for HRT and CaD participants to receive during their annual or semi-annual visits.

In addition, the A&R Working Group developed a survey that was completed by CC staff and investigators designed to elicit barriers to adherence and successful strategies for improving adherence in the CaD and HRT Trials. Surveys were returned by 38 CCs. Responses are being collated and synthesized to identify ways to assist CCs and to disseminate helpful suggestions.

Table 4.1
Calcium and Vitamin D Component Age – and Race/Ethnicity – Specific Recruitment

Data as of: August 31, 2001

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	**36,282**			
50-54	5157	118%	14%	10
55-59	8263	94%	23%	20
60-69	16522	84%	46%	45
70-79	6340	58%	17%	25
Race/Ethnicity	**36,282**			
American Indian	149		<1%	
Asian	721		2%	
Black	3315		9%	
Hispanic	1502		4%	
White	30155		83%	
Other/Unspecified	440		1%	

Table 4.2
CaD Adherence Summary
All CaD Participants

Data as of: August 31, 2001

	Due	Conducted		Conducted in Window		Stopped CaD		Missed Pill Collection		Total with Collections		Medication Rate[1] <50%		Medication Rate[1] 50%-80%		Medication Rate[1] 80% +		Adherence Summary[2]
	N	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	%
Semi-Annual Contact-2	33048	32213	97	26175	79	2022	6	4138	13	28882	88	4100	14	5786	20	18996	66	58
Annual Visit-2	33048	32266	98	25856	78	1403	4	2172	7	28185	93	2935	10	4847	17	20403	72	62
Annual Visit -3	36207	35096	97	26492	73	2229	6	2844	9	29468	91	2527	9	5015	17	21926	74	61
Annual Visit -4	28784	27395	95	19998	69	1346	5	1892	8	21993	92	1628	7	3218	15	17147	78	60
Annual Visit -5	16558	15611	94	11291	68	733	5	1001	8	12033	92	797	7	1696	14	9540	79	59
Annual Visit -6	7297	6835	94	4697	64	232	3	353	6	5141	94	334	7	658	13	4149	81	58
Annual Visit -7	1966	1800	92	1248	63	56	3	111	8	1361	93	78	6	157	12	1126	83	58

[1] Medication rate calculated as the number of pills taken divided by the number of days since bottle(s) were dispensed.
[2] Adherence summary calculated as the number of women consuming ≥80% of pills divided by the number due for a visit.
Note: Deceased women are excluded from all medication adherence calculations.

Table 4.3
CaD Drop-Out Rates by Follow-Up Time

Data as of: August 31, 2001

	Design			Observed			
	Int	Cum		Stopped[1]	Dead/ Lost[2]	Int[3]	Cum[4]
Drop-Outs[5]							
AV-2	8.8	8.8		10.1	0.6	10.8	10.8
AV-3	5.9	14.2		6.2	0.8	7.0	17.0
AV-4	5.9	19.2		4.7	0.8	5.5	21.6
AV-5	5.9	24.0		4.5	0.9	5.4	25.8
AV-6	5.9	28.5		3.2	0.9	4.1	28.9
AV-7	5.9	32.7		2.9	0.8	3.7	31.5

[1] Estimated rate of stopping CaD in the interval.
[2] Death or lost to follow-up rate in the interval.
[3] Combined rate of stopping and death or lost to follow-up in the interval.
[4] Estimated cumulative rate of stopping and death or lost to follow-up.
[5] Drop-out rates derived from Form 7 by date. Cumulative rates calculated as life-table estimates.

Figure 4.1
CaD Adherence Summary
% Participants Due for a Visit Who Took at Least 80% of Study Pills

Data as of: August 31, 2001

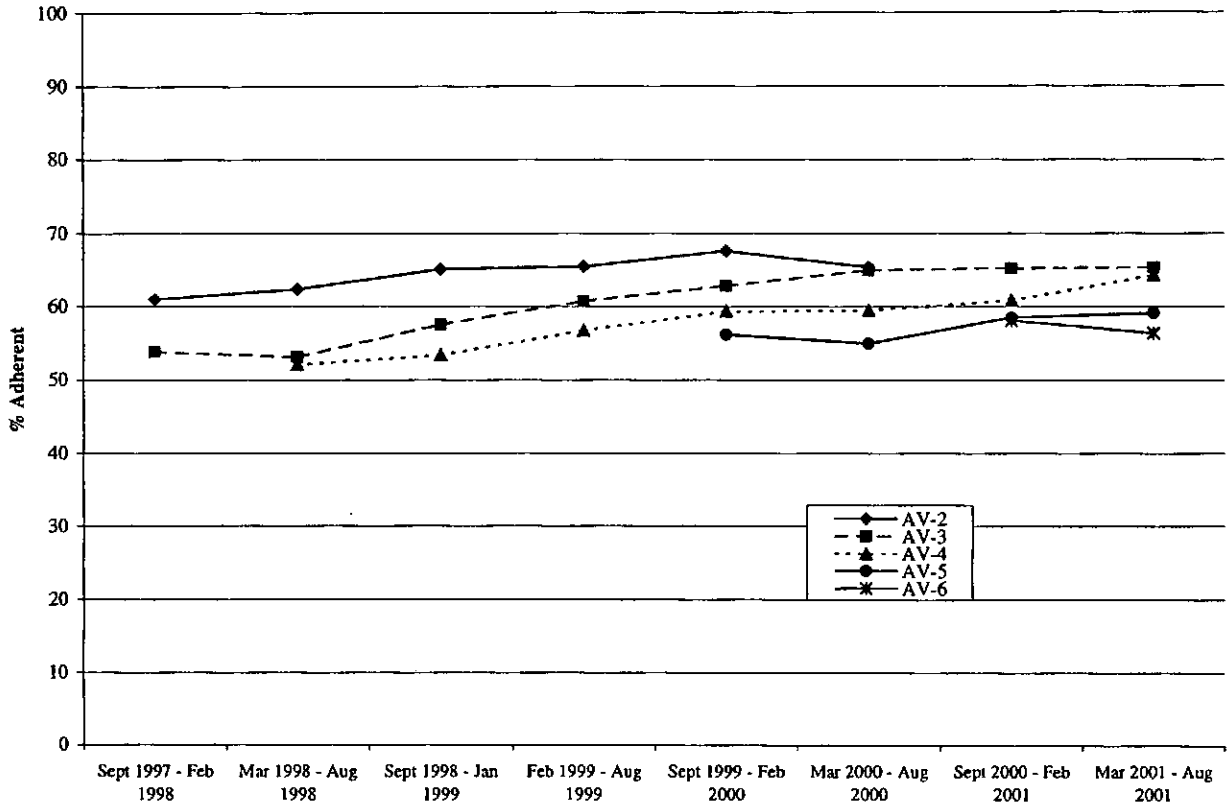


Table 4.4
Reasons for Stopping CaD[1]

Data as of: August 31, 2001

Reasons[2]	(N = 7956)	
Personal/family		
Demands of work	171	2.1%
Family illness, emergency or other family demands[3]	292	3.7%
Financial problems	11	0.1%
Lack of cooperation/support from family/friends[4]	42	0.5%
Living in nursing home	23	0.3%
Issues of interest in study[5]	224	2.8%
Travel		
Too far to CC	180	2.3%
Moved out of area or refuses to be followed at another CC	59	0.7%
Other travel issues[6]	75	0.9%
Visits & Procedures		
Doesn't like visits, calls	69	0.9%
Doesn't like required forms or safety procedures[7]	71	0.9%
Problems with other procedures[8]	27	0.3%
Worried about health effects of medical tests/procedures	30	0.4%
Wants results of blood analyses	3	<0.1%
Wants results of bone mineral density	2	<0.1%
Problems with CC[9]	44	0.6%

(continues)

[1] Does not include reasons reported by women who stopped and later restarted CaD.
[2] Multiple reasons may be reported for a woman.
[3] Combines "Family illness, emergency or other family demands", "Death in the family or of a close friend", and "Caregiver responsibilities demanding time, effort, lifestyle changes".
[4] Combines "Lack of cooperation/support from family and/or friends" and "Family/friends request that she withdraw".
[5] Combines "Conflicting priorities other than work or family", "Feels discouraged regarding participation overall", "Loss of interest, boredom", "Feels it is not an important study", and "In another study in conflict with WHI intervention".
[6] Combines "Transportation problems (other than distance)", "Traffic", "Parking at CC", and "CC neighborhood/safety".
[7] Combines "Doesn't like filling out forms (other than those required for safety)", and "Doesn't like required safety forms and/or procedures".
[8] Combines "Doesn't like mammograms", "Cost of mammograms", "Doesn't like having blood drawn", "Doesn't like ECG", "Doesn't like gynecologic procedures" and "Doesn't like other procedures (other than those required for safety)".
[9] Combines "Problem with the CC", "Problem with CC staff person (other than DM Group Nutritionist)", and "Staff change/turnover".

Table 4.4 (continued)
Reasons for Stopping CaD[1]

Data as of: August 31, 2001

Reasons[2]	(N = 7956)	
Symptoms		
Bloating/gas	135	1.7%
Constipation	163	2.0%
Other gastrointestinal problems	179	2.2%
HRT Related Symptoms[3]	37	0.5%
Other[4]	2309	29.0%
Health Conditions		
Hypercalcemia	88	1.1%
Renal calculi	93	1.2%
Osteoporosis	45	0.6%
Other Diseases/Health Conditions[5]	600	7.5%
Communication difficulties[6]	50	0.6%
Intervention		
Doesn't like randomized nature of intervention	342	4.3%
Expected some benefit from intervention	50	0.6%
Feels guilty, unhappy, or like a failure for not meeting study goals of intervention	19	0.2%
Takes too many pills	177	2.2%
Other pill issues[7]	907	11.4%
HRT Issues[8]	78	1.0%
DM Issues[9]	15	0.2%
Wants to take her own calcium	225	2.8%
Feels diet is already sufficient in calcium/Vit D	25	0.3%
Taking more than the max allowable IU of Vit D	19	0.2%
Taking Calcitrol	14	0.2%
Other Health Issues		
Worried about cost if adverse effects occur	9	0.1%
Expected more health care	20	0.3%
Advised not to participate by health care provider[10]	653	8.2%
Study conflicts with other health issues[11]	478	6.0%
Other		
Other reasons not listed above	1843	23.2%
Refuses to give a reason	130	1.6%

[1] Does not include reasons reported by women who stopped and later restarted CaD.
[2] Multiple reasons may be reported for a woman.
[3] Combines "Vaginal bleeding", "Breast tenderness", "Other breast changes", "Vaginal changes (e.g., dryness)", and "Hot flashes/night sweats".
[4] Combines "Experiencing health problems or symptoms not due to intervention", "Reports other health problems or symptoms from the WHI intervention", "Reports health problems or symptoms from the WHI intervention", "Hair/skin changes", "Headaches", "Weight loss/gain", "Low energy/too tired", "Possible allergic reaction", and "Other symptoms not listed above".
[5] Combines "Removed from intervention due to WHI symptom management", "Removed from intervention due to adverse health event", "Breast cancer", "Complex or atypical hyperplasia", "Endometrial cancer", "Deep vein thrombosis", "Pulmonary embolism", "Gallbladder disease", "Kidney failure/dialysis", "High triglycerides (> 1000 mg/dl)", "Malignant melanoma", "Meningioma", "Heart attack", "Stroke", "Arthritis", "Diabetes", "Depression", "Cholesterol (high or concern about levels)", and "Other health conditions not listed above".
[6] Combines "Communication problem", "Loss of vision and/or hearing", and "Cognitive/memory changes".
[7] Combines "Doesn't like taking pills", "Doesn't like taste of pills", and "Unable to swallow pills".
[8] Combines "Has made a personal decision to go on active HRT", "Has made a personal decision that she does not want to be on HRT", "Advised to go on active HRT by health care provider", "Advised to not be on active HRT by health care provider", "Has made a personal decision to go on SERM (e.g., Evista/raloxifene, tamoxifen)", "Advised to go on SERM (e.g., Evista/raloxifene, tamoxifen) by health care provider", and "Taking testosterone medications".
[9] Combines "Doesn't like DM requirements", "Problem with DM Group Nutritionist or group members", "Doesn't like DM eating pattern", "Doesn't like attending DM intervention classes", "Doesn't like self-monitoring", "Doesn't like budgeting fat grams", "Has concerns regarding long-term risks/benefits of low fat diet", "Unhappy that not losing weight", "Not in control of meal preparation", "Too difficult to meet or maintain dietary goals", "Doesn't like eating low fat diet", "Doesn't like eating 5 vegetables/fruits per day", "Doesn't like eating 6 grains per day", "Feels fat gram goal is unrealistic", and "Eating pattern conflicts with personal health beliefs".
[10] Combines "Advised not to participate by health care provider" and "Advised not to participate by health care provider for other reason".
[11] Combines "Study conflicts with health care needs" and "Study conflicts with other health issues".

Table 4.5
Reasons for Stopping CaD by Age at Screening and Race/Ethnicity[1]

Data as of August 31, 2001

			Age at Screening							
	All (N = 36,282)		50 – 54 (N = 5,157)		55 –59 (N = 8,263)		60 –69 (N = 16,522)		70 –79 (N = 6,340)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping CaD	7956	21.9%	1308	25.4%	1824	22.1%	3336	20.2%	1488	23.5%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Doesn't like randomized nature of intervention	342	4.3%	58	4.4%	75	4.1%	152	4.6%	57	3.8%
Other pill issues[5]	907	11.4%	142	10.9%	222	12.2%	381	11.4%	162	10.9%
Advised not to participate by health care provider[6]	653	8.2%	71	5.4%	141	7.7%	306	9.2%	135	9.1%
Study conflicts with other health issues[7]	478	6.0%	64	4.9%	96	5.3%	216	6.5%	102	6.9%

	Race/Ethnicity											
	American Indian/ Alaskan Native (N = 149)		Asian/Pacific Islander (N = 721)		Black/African American (N = 3,315)		Hispanic/Latino (N = 1,502)		White (N = 30,155)		Other/ Unspecified (N = 440)	
	N	%[8]	N	%[8]	N	%[8]	N	%[8]	N	%[8]	N	%[8]
Women Stopping CaD	36	24.2%	147	20.4%	826	24.9%	386	25.7%	6450	21.4%	111	25.2%
REASONS FOR STOPPING[3]	N	%[9]	N	%[9]	N	%[9]	N	%[9]	N	%[9]	N	%[9]
Doesn't like randomized nature of intervention	0	0.0%	3	2.0%	30	3.6%	8	2.1%	296	4.6%	5	4.5%
Other pill issues[5]	6	16.7%	19	12.9%	76	9.2%	46	11.9%	749	11.6%	11	9.9%
Advised not to participate by health care provider[6]	2	5.6%	6	4.1%	54	6.5%	28	7.3%	556	8.6%	7	6.3%
Study conflicts with other health issues[7]	3	8.3%	6	4.1%	37	4.5%	16	4.1%	410	6.4%	6	5.4%

[1] Does not include reasons reported by women who stopped and later restarted CaD.
[2] Percentages are of CaD participants in the same age category.
[3] Multiple reasons may be reported for a woman.
[4] Percentages are of CaD participants in the same age category who stopped CaD.
[5] Combines "Doesn't like taking pills", "Doesn't like taste of pills", and "Unable to swallow pills".
[6] Combines "Advised not to participate by health care provider" and "Advised not to participate by health care provider for other reason".
[7] Combines "Study conflicts with health care needs" and "Study conflicts with other health issues".
[8] Percentages are of CaD participants in the same race/ethnicity category.
[9] Percentages are of CaD participants in the same race/ethnicity category who stopped CaD.

Table 4.6
Bone Mineral Density[1] Analysis: CaD Participants

Data as of: August 31, 2001

	N	Mean	S.D.
Whole Body Scan			
AV1	2438	1.02	0.11
AV3	2280	1.03	0.11
AV6	978	1.05	0.12
AV3 % Change from AV1 BMD[2]	2207	1.46	3.39
AV6 % Change from AV1 BMD[3]	948	3.15	4.88
Spine Scan			
AV1	2364	0.99	0.17
AV3	2231	1.01	0.17
AV6	969	1.02	0.17
AV3 % Change from AV1 BMD[2]	2161	1.58	4.27
AV6 % Change from AV1 BMD[3]	941	2.94	5.92
Hip Scan			
AV1	2430	0.86	0.14
AV3	2283	0.87	0.14
AV6	992	0.88	0.14
AV3 % Change from AV1 BMD[2]	2209	1.28	3.55
AV6 % Change from AV1 BMD[3]	961	1.75	4.77

[1] Measured in (g/cm^2).
[2] Percent Change from BMD is defined as ((AV3-AV1)/AV1)x100.
[3] Percent Change from BMD is defined as ((AV6-AV1)/AV1)x100.

Table 4.7
Bone Mineral Density[1] Analysis: CaD Participants by Race/Ethnicity

Data as of: August 31, 2001

	Black/African American			Hispanic/Latino			White		
	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan									
AV1	278	1.08	0.11	123	1.04	0.12	1999	1.01	0.10
AV3	263	1.10	0.11	116	1.05	0.12	1865	1.03	0.11
AV6	83	1.10	0.12	37	1.13	0.17	842	1.05	0.12
AV3 % Change from AV1 BMD[2]	259	1.22	3.01	104	2.20	4.36	1810	1.45	3.38
AV6 % Change from AV1 BMD[3]	82	1.74	3.67	28	6.60	6.84	823	3.17	4.84
Spine Scan									
AV1	274	1.07	0.18	120	0.98	0.17	1932	0.98	0.16
AV3	260	1.08	0.19	115	0.97	0.15	1820	1.00	0.17
AV6	86	1.10	0.16	36	0.99	0.17	831	1.01	0.17
AV3 % Change from AV1 BMD[2]	256	1.15	4.40	102	0.07	4.88	1769	1.76	4.19
AV6 % Change from AV1 BMD[3]	85	0.64	5.96	27	1.97	6.18	814	3.18	5.87
Hip Scan									
AV1	279	0.98	0.14	123	0.87	0.14	1990	0.85	0.13
AV3	264	0.98	0.15	116	0.88	0.13	1867	0.86	0.13
AV6	88	1.00	0.14	37	0.90	0.16	851	0.87	0.13
AV3 % Change from AV1 BMD[2]	260	0.85	3.16	103	1.68	4.67	1812	1.32	3.52
AV6 % Change from AV1 BMD[3]	86	-0.47	4.23	28	3.89	3.68	832	1.90	4.78

[1] Measured in (g/cm^2).
[2] Percent Change from BMD is defined as ((AV3-AV1)/AV1)x100.
[3] Percent Change from BMD is defined as ((AV6-AV1)/AV1)x100.

Table 4.8
Lost-to-Follow-up and Vital Status: CaD Participants

Data as of: August 31, 2001

	CaD Participants (N=36,282)	
	N	%
Vital Status/Participation		
Deceased	555	1.5
Alive: Current Participation[1]	34514	95.1
Alive: Recent Participation[2]	580	1.6
Alive: Past/Unknown Participation[3]	37	0.1
Stopped Follow-Up[4]	320	0.9
Lost to Follow-Up[5]	276	0.8

[1] Participants who have filled in a Form 33 within the last 9 months.
[2] Participants who last filled in a Form 33 between 9 and 18 months ago.
[3] Participiants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.
[5] Participants not in any of the above categories.

Table 4.9
Locally Verified Outcomes (Annualized Percentages) by Age for Calcium and Vitamin D

Data as of: August 31, 2001

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number of participants	36282	5157	8263	16522	6340
Mean follow-up (months)	43.1	48.7	45.1	41.4	40.5
Fractures					
Hip fracture	123 (0.09%)	4 (0.02%)	11 (0.04%)	49 (0.09%)	59 (0.28%)
Vertebral fracture	126 (0.10%)	5 (0.02%)	12 (0.04%)	50 (0.09%)	59 (0.28%)
Other fracture[1]	1806 (1.38%)	229 (1.09%)	364 (1.17%)	834 (1.46%)	379 (1.77%)
Total fracture	1994 (1.53%)	237 (1.13%)	385 (1.24%)	906 (1.59%)	466 (2.18%)
Cancer					
Colorectal cancer	153 (0.12%)	12 (0.06%)	26 (0.08%)	72 (0.13%)	43 (0.20%)
Breast cancer[2]	615 (0.47%)	72 (0.34%)	147 (0.47%)	293 (0.51%)	103 (0.48%)
Invasive breast cancer	488 (0.37%)	56 (0.27%)	117 (0.38%)	230 (0.40%)	85 (0.40%)
Non-invasive breast cancer	130 (0.10%)	16 (0.08%)	31 (0.10%)	64 (0.11%)	19 (0.09%)
Ovary cancer	57 (0.04%)	8 (0.04%)	13 (0.04%)	23 (0.04%)	13 (0.06%)
Endometrial cancer[3]	82 (0.11%)	12 (0.10%)	19 (0.10%)	38 (0.11%)	13 (0.11%)
Other cancer[1]	602 (0.46%)	53 (0.25%)	106 (0.34%)	286 (0.50%)	157 (0.73%)
Total cancer	1478 (1.13%)	156 (0.74%)	303 (0.97%)	700 (1.23%)	319 (1.49%)
Cardiovascular					
CHD[4]	390 (0.30%)	28 (0.13%)	39 (0.13%)	183 (0.32%)	140 (0.65%)
CHD death[5]	83 (0.06%)	8 (0.04%)	8 (0.03%)	33 (0.06%)	34 (0.16%)
Total MI[6]	332 (0.25%)	22 (0.11%)	33 (0.11%)	161 (0.28%)	116 (0.54%)
Clinical MI	311 (0.24%)	18 (0.09%)	32 (0.10%)	150 (0.26%)	111 (0.52%)
Evolving Q-wave MI[7]	30 (0.02%)	5 (0.02%)	1 (<0.01%)	16 (0.03%)	8 (0.04%)
Possible evolving Q-wave MI[7]	98 (0.08%)	10 (0.05%)	18 (0.06%)	40 (0.07%)	30 (0.14%)
Angina	541 (0.41%)	26 (0.12%)	72 (0.23%)	258 (0.45%)	185 (0.86%)
CABG/PTCA	525 (0.40%)	26 (0.12%)	66 (0.21%)	250 (0.44%)	183 (0.85%)
Carotid artery disease	100 (0.08%)	3 (0.01%)	11 (0.04%)	46 (0.08%)	40 (0.19%)
Congestive heart failure	308 (0.24%)	12 (0.06%)	37 (0.12%)	138 (0.24%)	121 (0.56%)
Stroke	280 (0.21%)	13 (0.06%)	32 (0.10%)	117 (0.21%)	118 (0.55%)
PVD	73 (0.06%)	3 (0.01%)	10 (0.03%)	29 (0.05%)	31 (0.14%)
CHD[4]/Possible evolving Q-wave MI	476 (0.37%)	38 (0.18%)	55 (0.18%)	218 (0.38%)	165 (0.77%)
Coronary disease[8]	1197 (0.92%)	71 (0.34%)	156 (0.50%)	557 (0.98%)	413 (1.93%)
Total cardiovascular disease	1559 (1.20%)	87 (0.42%)	199 (0.64%)	724 (1.27%)	549 (2.56%)
Deaths					
Cardiovascular deaths	158 (0.12%)	11 (0.05%)	13 (0.04%)	63 (0.11%)	71 (0.33%)
Cancer deaths	263 (0.20%)	19 (0.09%)	33 (0.11%)	126 (0.22%)	85 (0.40%)
Deaths: other known cause	63 (0.05%)	3 (0.01%)	9 (0.03%)	25 (0.04%)	26 (0.12%)
Deaths: unknown cause	25 (0.02%)	1 (<0.01%)	5 (0.02%)	11 (0.02%)	8 (0.04%)
Deaths: not yet adjudicated	46 (0.04%)	3 (0.01%)	2 (0.01%)	26 (0.05%)	15 (0.07%)
Total death	555 (0.43%)	37 (0.18%)	62 (0.20%)	251 (0.44%)	205 (0.96%)

[1] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

[2] Excludes four cases with borderline malignancy.

[3] Only women without a baseline hysterectomy are used to compute the annual rates of Endometrial cancer.

[4] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death. This definition has changed slightly from the February 2001 report.

[5] "CHD death" includes definite and possible CHD death. This definition has changed slightly from the February 2001 report.

[6] "Total MI" includes clinical MI and evolving Q-wave MI.

[7] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.

[8] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

Table 4.9 (Continued)
Locally Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Calcium and Vitamin D

Data as of: August 31, 2001

Outcome	Race/Ethnicity: American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Other/ Unspecified
Number of participants	149	721	3315	1502	30155	440
Mean follow-up (months)	42.8	39.5	41.9	41.3	43.5	39.1
Fractures						
Hip fracture	0 (0.00%)	1 (0.04%)	2 (0.02%)	1 (0.02%)	119 (0.11%)	0 (0.00%)
Vertebral fracture	0 (0.00%)	2 (0.08%)	0 (0.00%)	4 (0.08%)	117 (0.11%)	3 (0.21%)
Other fracture[1]	8 (1.51%)	23 (0.97%)	89 (0.77%)	44 (0.85%)	1628 (1.49%)	14 (0.98%)
Total fracture	8 (1.51%)	25 (1.05%)	91 (0.79%)	49 (0.95%)	1805 (1.65%)	16 (1.12%)
Cancer						
Colorectal cancer	2 (0.38%)	3 (0.13%)	16 (0.14%)	7 (0.14%)	124 (0.11%)	1 (0.07%)
Breast cancer[2]	1 (0.19%)	9 (0.38%)	34 (0.29%)	15 (0.29%)	554 (0.51%)	2 (0.14%)
Invasive breast cancer	1 (0.19%)	8 (0.34%)	27 (0.23%)	12 (0.23%)	438 (0.40%)	2 (0.14%)
Non-invasive breast cancer	0 (0.00%)	1 (0.04%)	8 (0.07%)	3 (0.06%)	118 (0.11%)	0 (0.00%)
Ovary cancer	1 (0.19%)	1 (0.04%)	5 (0.04%)	0 (0.00%)	50 (0.05%)	0 (0.00%)
Endometrial cancer[3]	1 (0.46%)	0 (0.00%)	2 (0.04%)	2 (0.07%)	76 (0.12%)	1 (0.12%)
Other cancer[1]	2 (0.38%)	11 (0.46%)	34 (0.29%)	14 (0.27%)	536 (0.49%)	5 (0.35%)
Total cancer	7 (1.32%)	24 (1.01%)	91 (0.79%)	35 (0.68%)	1312 (1.20%)	9 (0.63%)
Cardiovascular						
CHD[4]	1 (0.19%)	0 (0.00%)	37 (0.32%)	10 (0.19%)	340 (0.31%)	2 (0.14%)
CHD death[5]	0 (0.00%)	0 (0.00%)	16 (0.14%)	2 (0.04%)	64 (0.06%)	1 (0.07%)
Total MI[6]	1 (0.19%)	0 (0.00%)	24 (0.21%)	9 (0.17%)	296 (0.27%)	2 (0.14%)
Clinical MI	1 (0.19%)	0 (0.00%)	21 (0.18%)	9 (0.17%)	278 (0.25%)	2 (0.14%)
Evolving Q-wave MI[7]	0 (0.00%)	0 (0.00%)	3 (0.03%)	0 (0.00%)	27 (0.02%)	0 (0.00%)
Possible evolving Q-wave MI[7]	0 (0.00%)	3 (0.13%)	14 (0.12%)	3 (0.06%)	78 (0.07%)	0 (0.00%)
Angina	1 (0.19%)	5 (0.21%)	51 (0.44%)	21 (0.41%)	457 (0.42%)	6 (0.42%)
CABG/PTCA	1 (0.19%)	3 (0.13%)	39 (0.34%)	18 (0.35%)	458 (0.42%)	6 (0.42%)
Carotid artery disease	1 (0.19%)	2 (0.08%)	5 (0.04%)	0 (0.00%)	92 (0.08%)	0 (0.00%)
Congestive heart failure	0 (0.00%)	2 (0.08%)	38 (0.33%)	10 (0.19%)	253 (0.23%)	5 (0.35%)
Stroke	3 (0.56%)	9 (0.38%)	29 (0.25%)	7 (0.14%)	227 (0.21%)	5 (0.35%)
PVD	1 (0.19%)	0 (0.00%)	13 (0.11%)	0 (0.00%)	58 (0.05%)	1 (0.07%)
CHD[4]/Possible evolving Q-wave MI	1 (0.19%)	3 (0.13%)	49 (0.42%)	13 (0.25%)	408 (0.37%)	2 (0.14%)
Coronary disease[8]	1 (0.19%)	11 (0.46%)	125 (1.08%)	38 (0.73%)	1010 (0.92%)	12 (0.84%)
Total cardiovascular disease	5 (0.94%)	20 (0.84%)	164 (1.42%)	45 (0.87%)	1307 (1.20%)	18 (1.26%)
Deaths						
Cardiovascular deaths	0 (0.00%)	2 (0.08%)	28 (0.24%)	3 (0.06%)	124 (0.11%)	1 (0.07%)
Cancer deaths	0 (0.00%)	7 (0.29%)	21 (0.18%)	3 (0.06%)	229 (0.21%)	3 (0.21%)
Deaths: other known cause	1 (0.19%)	0 (0.00%)	8 (0.07%)	0 (0.00%)	53 (0.05%)	1 (0.07%)
Deaths: unknown cause	1 (0.19%)	0 (0.00%)	3 (0.03%)	0 (0.00%)	21 (0.02%)	0 (0.00%)
Deaths: not yet adjudicated	0 (0.00%)	4 (0.17%)	3 (0.03%)	1 (0.02%)	38 (0.03%)	0 (0.00%)
Total death	2 (0.38%)	13 (0.55%)	63 (0.54%)	7 (0.14%)	465 (0.43%)	5 (0.35%)

[1] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.
[2] Excludes four cases with borderline malignancy.
[3] Only women without a baseline hysterectomy are used to compute the annual rates of Endometrial cancer.
[4] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death. This definition has changed slightly from the February 2001 report.
[5] "CHD death" includes definite and possible CHD death. This definition has changed slightly from the February 2001 report.
[6] "Total MI" includes clinical MI and evolving Q-wave MI.
[7] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[8] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

Table 4.10
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for CaD Participants who did not report a prevalent condition at baseline

Data as of: August 31, 2001

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	36282	5157	8263	16522	6340
Mean follow-up (months)	43.1	48.7	45.1	41.4	40.5
Hospitalizations					
Ever	9897 (7.59%)	1060 (5.06%)	1862 (5.99%)	4678 (8.22%)	2297 (10.72%)
Two or more	3677 (2.82%)	346 (1.65%)	615 (1.98%)	1711 (3.00%)	1005 (4.69%)
Other					
DVT[1]	195 (0.15%)	13 (0.06%)	38 (0.13%)	80 (0.14%)	64 (0.31%)
Pulmonary embolism	103 (0.08%)	6 (0.03%)	21 (0.07%)	50 (0.09%)	26 (0.12%)
Diabetes (treated)	1338 (1.07%)	207 (1.02%)	317 (1.06%)	592 (1.09%)	222 (1.09%)
Gallbladder disease[2]	1336 (1.21%)	197 (1.06%)	348 (1.30%)	604 (1.28%)	187 (1.07%)
Hysterectomy	506 (0.66%)	73 (0.61%)	122 (0.64%)	237 (0.72%)	74 (0.62%)
Glaucoma	1762 (1.40%)	181 (0.88%)	343 (1.13%)	846 (1.55%)	392 (1.96%)
Osteoporosis	3705 (2.98%)	338 (1.64%)	654 (2.17%)	1803 (3.34%)	910 (4.67%)
Osteoarthritis[3]	3667 (4.55%)	517 (3.39%)	842 (4.02%)	1688 (5.05%)	620 (5.69%)
Rheumatoid arthritis	965 (0.77%)	147 (0.72%)	236 (0.78%)	408 (0.75%)	174 (0.85%)
Intestinal polyps	2350 (1.93%)	289 (1.42%)	508 (1.71%)	1147 (2.17%)	406 (2.12%)
Lupus	162 (0.12%)	31 (0.15%)	37 (0.12%)	68 (0.12%)	26 (0.12%)
Kidney stones[3]	319 (0.32%)	43 (0.28%)	80 (0.34%)	146 (0.32%)	50 (0.30%)
Cataracts[3]	5808 (6.51%)	345 (2.30%)	931 (4.09%)	3139 (7.91%)	1393 (11.91%)
Pills for hypertension	5076 (5.43%)	678 (3.96%)	1152 (4.80%)	2276 (5.81%)	970 (7.36%)

Outcomes	Race/Ethnicity: American Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Other/ Unspecified
Number randomized	149	721	3315	1502	30155	440
Mean follow-up (months)	42.8	39.5	41.9	41.3	43.5	39.1
Hospitalizations						
Ever	42 (7.90%)	114 (4.80%)	935 (8.07%)	330 (6.38%)	8366 (7.65%)	110 (7.67%)
Two or more	22 (4.14%)	38 (1.60%)	347 (3.00%)	114 (2.20%)	3120 (2.85%)	36 (2.51%)
Other						
DVT[1]	2 (0.39%)	0 (0.00%)	14 (0.12%)	4 (0.08%)	174 (0.16%)	1 (0.07%)
Pulmonary embolism	2 (0.38%)	0 (0.00%)	8 (0.07%)	2 (0.04%)	89 (0.08%)	2 (0.14%)
Diabetes (treated)	7 (1.42%)	38 (1.70%)	237 (2.29%)	94 (1.93%)	947 (0.89%)	15 (1.11%)
Gallbladder disease[2]	7 (1.77%)	25 (1.16%)	90 (0.86%)	63 (1.58%)	1137 (1.24%)	14 (1.17%)
Hysterectomy	1 (0.46%)	6 (0.39%)	22 (0.44%)	12 (0.42%)	461 (0.70%)	4 (0.50%)
Glaucoma	11 (2.17%)	30 (1.31%)	228 (2.10%)	87 (1.73%)	1393 (1.32%)	13 (0.95%)
Osteoporosis	11 (2.18%)	70 (3.05%)	166 (1.48%)	139 (2.86%)	3270 (3.14%)	49 (3.66%)
Osteoarthritis[3]	19 (5.73%)	69 (4.06%)	333 (4.75%)	191 (5.45%)	3011 (4.49%)	44 (4.75%)
Rheumatoid arthritis	9 (1.92%)	17 (0.75%)	167 (1.56%)	84 (1.70%)	674 (0.64%)	14 (1.03%)
Intestinal polyps	13 (2.65%)	38 (1.73%)	217 (2.00%)	82 (1.65%)	1975 (1.93%)	25 (1.89%)
Lupus	3 (0.57%)	1 (0.04%)	16 (0.14%)	5 (0.10%)	136 (0.12%)	1 (0.07%)
Kidney stones[3]	2 (0.50%)	6 (0.32%)	18 (0.21%)	23 (0.58%)	266 (0.32%)	4 (0.35%)
Cataracts[3]	30 (8.09%)	98 (5.93%)	471 (5.93%)	230 (6.13%)	4918 (6.61%)	61 (6.03%)
Pills for hypertension	20 (6.00%)	98 (6.03%)	522 (8.63%)	234 (5.85%)	4143 (5.15%)	59 (6.42%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 4.11
Sensitivity of CaD Study Power to Adherence and Incidence Rate Assumptions
Revised Sample Size of 36,282

	Year	Intervention Effect[1] (%)	Percentage of Cases[1] Control	Intervention	Design[2]	Revised Assumptions[3]
Hip Fractures						
	2001	20	1.61	1.36	57	24
		27	1.62	1.31	74	33
		33	1.62	1.26	86	43
	2004	20	2.84	2.35	86	51
		27	2.85	2.25	96	67
		33	2.85	2.15	99	81
Combined Fractures[4]						
	2001	19	6.48	5.54	98	79
		23	6.50	5.36	>99	92
		28	6.51	5.18	>99	98
	2004	19	10.22	8.62	>99	99
		23	10.24	8.30	>99	>99
		28	10.25	7.98	>99	>99
Colorectal Cancer						
	2001	18	0.90	0.80	22	14
		20	0.90	0.79	26	17
		22	0.90	0.78	30	19
	2004	18	1.48	1.22	68	46
		20	1.49	1.20	77	55
		22	1.49	1.18	84	62

[1] Intervention Effects and Percentage of Cases are shown for original Design assumptions. The other adherence patterns would produce greater incidence rates in Intervention women and a corresponding reduction in the estimated treatment effect.
[2] For design, the calculations were based on n = 35,000.
[3] For revised assumption, calculations were based on n = 36,282 and 7.5 years of follow-up for years 1 though 9. Control incidence rates for years 1-4 were based on observed data and adjustment thereafter accordingly.
[4] Proximal femur, distal forearm, proximal humerus, pelvis, vertebra.

5. Observational Study

5.1 Recruitment

Recruitment into the OS component, completed in December of 1998, reached 93,717, approximately 94% of the expected sample size. After removing duplicate enrollments and a few enrollments with insufficient data, the final analytic cohort was established with 93,676 participants. *Table 5.1* documents the age distribution and the racial/ethnic composition of this cohort.

5.2 Overview of Follow-up

OS follow-up is conducted by annual mailed self-administered questionnaires except for year 3, when participants attend a clinic follow-up visit. Approximately 2 months prior to the anniversary of the participants' enrollment, the CCC mails the Medical History Update and the OS Exposure Update questionnaires. Participants mail their completed questionnaires to their local CC for data entry and outcomes processing. Non-respondents receive up to two additional mailings from the CCC. For odd numbered follow-up years, CCs attempt to complete follow-up of non-responders by local contacts, usually telephone reminders or interviews.

The year 3 clinic visit was incorporated to assess change in physical measures, blood analytes, diet, and use of medications and supplements. These visits began in the first VCCs in Fall 1997.

5.3 Completeness of Annual Mail Follow-up

Table 5.2 shows completeness of OS mail follow-up by follow-up year, type of contact, and clinic group. These rates include participants for whom the full sequence of mailings are complete and there has been at least two months for CC follow-up of non-responders.

The overall response of 95.7% for year 1 data collection, which includes mailings plus CC follow-up of non-responders, slightly exceeds the 95% goal for completion of the OS Exposure Update (*Form 48*), but falls short of the optimal goal (98%) for completion of the Medical History Update (*Form 33*). For years 2, 4, and 5, the rates of 94.2% (Y2), 93.3% (Y4), and 95.5% (Y5) exceed the 94% (Y2), 92% (Y4), and 91% (Y5) goals for the Exposure Update.

5.4 Completeness of Year 3 Clinic Visit

Table 5.3 shows completeness of activities conducted at the year 3 clinic visit. Of those participants due for the year 3 visit through 10/31/00, 95.6% overall completed medical history updates (*Form 33*) and 82.3% provided blood samples (*Form 100*).

5.5 Bone Mineral Density

Bone scans are given to all enrolled WHI participants in three Clinical Centers: Birmingham, Pittsburgh, and Tucson. The choice of three centers was based on reducing the variability associated with multiple sites and operators while achieving adequate sample size. The selection of these three Clinical Centers was based both on their previous experience in bone densitometry and the expected enrollment of minorities which will allow us to address hypotheses regarding racial/ethnic differences. Bone scans are given at baseline and years 1, 3, 6, and 9 in these centers.

Tables 5.4 (overall) and *Table 5.5* (by race and ethnicity) show the OS component-specific BMD means and standard deviations for baseline AV-3 along with % change from baseline for the three

types of scans available: whole body, spine, and hip. Baseline and % change is also given using only those women who have an AV-3 bone scan, as nearly 3,000 of the women with a baseline do not have an AV-3 measure. The current data suggest overall a small increase in bone density over three years in this group of women. In general, we would have expected a small decrease in BMD over time. As with the corresponding DM results, this increase could be related to some selection of health conscious women who may be taking hormone replacement therapy or calcium supplements of their own, or could be due to measurement issues.

5.6 Vital Status

Table 5.6 presents data on the vital status and the participation status of participants in the OS. A detailed description of CC and CCC activities to actively locate participants who do not complete their periodic visits is given in *Section 6 – Outcomes.* For operational purposes, we define OS participants to be lost-to-follow-up if there is no outcomes information from the participant for 24 months. Currently 1.8% of the participants are lost-to-follow-up, and an additional 1.2% of the participants have stopped follow-up. 2.4% of the OS participants are deceased. Compared to six months ago, the percentage of participants who were lost-to-follow-up or stopped follow-up increased by 0.2%. Over the same period, participation levels have declined, as only 89.7% of the participants are considered current, and 4.9% have either recent or past participation. In contrast, six months ago 92.0% were current and 3.0% had recent or past participation.

5.7 Outcomes

Table 5.7 contains counts of the number of locally verified major WHI outcomes for OS participants by age and race/ethnicity. As approximately 6% of the self-reported outcomes have not yet been verified, the numbers in this table can be seen as a lower bound to the actual number of outcomes that took place. Compared to the incidence rates used in the CT design, we have about 85% of the expected number of breast cancers, 65% of the expected number of colorectal cancers, about 50% of the expected number of CHD events, and about 35% of the expected number hip fractures. For most outcomes categories there are now hundreds of events, which should make it possible to do interesting etiological analyses.

Table 5.8 contains counts of the number of self-reports for some outcomes that are not locally verified in WHI. As most of the locally verified outcomes are somewhat over-reported (see *Section 6.3 – Outcomes Data Quality*), the number in this table should be taken as an upper bound to the number of events that have occurred among OS participants.

Tables 5.9 and 5.10, which are new in this report, contain counts of outcomes relative to their AV-3. These tables count the *first* event of a particular type, thus a participant who reports, say, an Angina at AV-1 and another one at AV-4 gets only counted in the "Before AV-3" category. These tables may be particularly useful for investigators who want to propose ancillary studies or papers.

Table 5.1
Observational Study Age and Race/Ethnicity Specific Recruitment

Data as of: August 31, 2001

	Total Enrolled	Distribution
Age	**93,676**	
50-54	12386	13%
55-59	17321	18%
60-69	41196	44%
70-79	22773	24%
Race/Ethnicity	**93,676**	
American Indian	421	<1%
Asian	2671	3%
Black	7634	8%
Hispanic	3608	4%
White	78018	83%
Other/Unspecified	1324	1%

Table 5.2
Response Rates to OS Follow-up Procedures

Data as of: August 31, 2001

	# Due[1]	Mailings Initiated[2] N	Mailings Initiated[2] %	Response to Mailings N	Response to Mailings %[3]	Response to CC follow-up N	Response to CC follow-up %[4]	Total Responses N	Total Responses %[5]
Year 1	93,473	93,288	99.8%	86,654	92.9%	2,829	42.6%	89,483	95.7%
VCC	41,637	41,604	99.9%	38,419	92.3%	1,689	53.0%	40,108	96.3%
NCC	51,836	51,684	99.7%	48,235	93.3%	1,140	33.1%	49,375	95.3%
Year 2	92,248	90,624	98.2%	85,610	94.5%	N/A		86,886	94.2%
VCC	41,426	40,680	98.2%	38,453	94.5%	N/A		39,067	94.3%
NCC	50,822	49,944	98.3%	47,157	94.4%	N/A		47,819	94.1%
Year 4	42,081	41,200	97.9%	38,356	93.1%	N/A		39,252	93.3%
VCC	20,336	19,828	97.5%	18,413	92.9%	N/A		18,784	92.4%
NCC	21,745	21,372	98.3%	19,943	93.3%	N/A		20,468	94.1%
Year 5	13,842	13,666	98.7%	12,948	94.7%	274	38.2%	13,222	95.5%
VCC	8,712	8,623	99.0%	8,111	94.1%	205	40.0%	8,316	95.5%
NCC	5,130	5,043	98.3%	4,837	95.9%	69	33.5%	4,906	95.6%

[1] Excludes women who are deceased.
[2] Mailings are not sent to women who have requested no follow-up, who are deceased, who have a non-deliverable address at the time of mailing, or who have a Form 33 completed within the previous 3 months.
[3] Percent response of those initiated.
[4] Percent response from OS participants not responding to mailings. CC follow-up not required in even numbered follow-up years.
[5] Percent response of those due.

Table 5.3
OS Annual Visit 3 Task Completeness

Data as of: August 31, 2001

Task	# Due[1]	# Done[2]	% Done
Form 33 - Medical History Update	68,863	65,823	95.6%
Form 38 - Daily Life	68,863	60,886	88.4%
Form 44 - Current Medications	68,863	58,560	85.0%
Form 45 - Current Supplements	68,863	58,477	84.9%
Form 60 - Food Frequency Quest	68,863	60,965	88.5%
Form 80 - Physical Measures	68,863	57,277	83.2%
Form 100 - Blood Collection	68,863	56,693	82.3%
Form 143 - Follow-up	68,863	60,614	88.0%

[1] Includes all Year 3 contacts due through 10/31/2000. Excludes women who are deceased.
[2] Tasks completed within the -6/+15 months window.

Table 5.4
Bone Mineral Density[1] Analysis: OS Participants

Data as of: August 31, 2001

	N	Mean	S.D.
Whole Body Scan			
Baseline	6413	1.01	0.11
Baseline (for ppts. with an AV3 scan)	5001	1.01	0.11
Baseline (for ppts. with an AV6 scan)	1501	1.02	0.11
AV3	5053	1.02	0.11
AV6	1509	1.03	0.12
AV3 % Change from baseline BMD[2]	4994	0.98	3.68
AV6 % Change from baseline BMD[3]	1498	1.75	5.33
Spine Scan			
Baseline	6295	0.98	0.17
Baseline (for ppts. with an AV3 scan)	4934	0.97	0.17
Baseline (for ppts. with an AV6 scan)	1463	0.98	0.17
AV3	4968	0.99	0.18
AV6	1467	1.01	0.18
AV3 % Change from baseline BMD[2]	4926	1.69	5.15
AV6 % Change from baseline BMD[3]	1460	3.41	6.88
Hip Scan			
Baseline	6415	0.84	0.14
Baseline (for ppts. with an AV3 scan)	5041	0.84	0.14
Baseline (for ppts. with an AV6 scan)	1508	0.84	0.13
AV3	5078	0.85	0.14
AV6	1513	0.84	0.14
AV3 % Change from baseline BMD[2]	5009	0.55	4.33
AV6 % Change from baseline BMD[3]	1494	0.38	5.31

[1] Measured in (g/cm^2).
[2] AV3 % Change from baseline BMD is defined as ((AV3-Baseline)/Baseline)x100.
[3] AV6 % Change from baseline BMD is defined as ((AV6-Baseline)/Baseline)x100.

Table 5.5
Bone Mineral Density[1] Analysis: OS Participants by Race/Ethnicity

Data as of: August 31, 2001

	American Indian/ Alaskan Native			Asian/Pacific Islander			Black/African American			Hispanic/Latino			White			Other/Unspecified		
	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan																		
Baseline	108	1.01	0.12	25	1.02	0.09	828	1.05	0.11	463	1.01	0.11	4943	1.01	0.10	46	1.01	0.12
Baseline (for ppts. with an AV3 scan)	67	1.02	0.11	22	1.03	0.09	563	1.05	0.11	314	1.01	0.10	4001	1.01	0.10	34	1.01	0.12
Baseline (for ppts. with an AV6 scan)	5	1.14	0.09	7	1.00	0.09	112	1.07	0.10	38	1.04	0.11	1330	1.01	0.10	9	1.03	0.15
AV3	69	1.02	0.12	22	1.03	0.11	570	1.06	0.12	329	1.03	0.11	4028	1.01	0.11	35	1.01	0.11
AV6	5	1.21	0.07	7	1.03	0.15	113	1.07	0.11	38	1.09	0.16	1337	1.03	0.12	9	1.03	0.15
AV3 % Change from baseline BMD[2]	67	0.24	4.07	22	-0.03	5.44	563	1.60	3.29	313	1.45	4.39	3995	0.88	3.65	34	0.36	2.82
AV6 % Change from baseline BMD[3]	5	5.71	2.85	7	2.69	6.03	112	0.67	3.44	38	4.36	6.88	1327	1.76	5.40	9	0.56	3.55
Spine Scan																		
Baseline	109	0.99	0.17	25	0.95	0.12	820	1.04	0.18	456	0.95	0.16	4839	0.97	0.17	46	0.99	0.19
Baseline (for ppts. with an AV3 scan)	67	0.99	0.15	22	0.96	0.12	567	1.04	0.18	309	0.95	0.16	3935	0.97	0.17	34	0.95	0.18
Baseline (for ppts. with an AV6 scan)	5	1.10	0.11	6	0.90	0.11	107	1.07	0.16	38	0.99	0.19	1298	0.97	0.16	9	1.03	0.32
AV3	69	0.99	0.15	22	0.96	0.12	569	1.05	0.19	322	0.95	0.16	3951	0.98	0.17	35	0.95	0.17
AV6	5	1.14	0.08	6	0.90	0.10	107	1.11	0.19	38	0.99	0.19	1302	1.00	0.18	9	1.08	0.33
AV3 % Change from baseline BMD[2]	67	-0.21	5.68	22	0.22	4.62	567	1.16	5.58	308	0.20	5.33	3928	1.93	5.03	34	0.84	5.17
AV6 % Change from baseline BMD[3]	5	3.62	6.25	6	0.30	4.05	107	3.24	6.18	38	0.55	7.14	1295	3.51	6.92	9	4.55	7.72
Hip Scan																		
Baseline	109	0.87	0.15	25	0.82	0.10	827	0.93	0.15	463	0.83	0.13	4945	0.83	0.13	46	0.85	0.14
Baseline (for ppts. with an AV3 scan)	67	0.88	0.16	22	0.82	0.10	572	0.93	0.15	315	0.83	0.12	4031	0.83	0.13	34	0.83	0.12
Baseline (for ppts. with an AV6 scan)	5	0.99	0.07	7	0.75	0.08	113	0.93	0.15	38	0.85	0.14	1335	0.83	0.13	10	0.84	0.18
AV3	69	0.88	0.15	22	0.82	0.09	577	0.94	0.15	329	0.85	0.12	4046	0.83	0.13	35	0.82	0.13
AV6	5	1.03	0.08	7	0.78	0.09	113	0.93	0.15	38	0.88	0.14	1340	0.83	0.13	10	0.83	0.18
AV3 % Change from baseline BMD[2]	66	-0.06	5.17	22	0.81	4.42	572	0.46	3.92	313	1.70	5.07	4002	0.49	4.29	34	-0.33	4.40
AV6 % Change from baseline BMD[3]	5	4.01	0.83	7	4.04	6.76	113	-0.86	4.28	38	2.73	5.04	1321	0.40	5.36	10	-0.75	6.21

[1] Measured in (g/cm^2).
[2] AV3 % Change from baseline BMD is defined as ((AV3-Baseline)/Baseline)x100.
[3] AV6 % Change from baseline BMD is defined as ((AV6-Baseline)/Baseline)x100.

Table 5.6
Lost-to-Follow-up and Vital Status: OS Participants

Data as of: August 31, 2001

	OS Participants (N=93,676)	
	N	%
Vital Status/Participation		
Deceased	2202	2.4
Alive: Current Participation[1]	84038	89.7
Alive: Recent Participation[2]	4400	4.7
Alive: Past/Unknown Participation[3]	218	0.2
Stopped Follow-Up[4]	1115	1.2
Lost to Follow-Up[5]	1703	1.8

[1] Participants who have filled in a Form 33 within the last 15 months.
[2] Participants who last filled in a Form 33 between 15 and 24 months ago.
[3] Participants without a Form 33 within the last 24 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.
[5] Participants not in any of the above categories.

Table 5.7
Locally Verified Outcomes (Annualized Percentages) by Age for OS Participants

Data as of: August 31, 2001

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number enrolled	93676	12386	17321	41196	22773
Mean follow-up (months)	49.2	52.6	51.4	48.1	47.6
Cardiovascular					
CHD[1]	1006 (0.26%)	29 (0.05%)	90 (0.12%)	399 (0.24%)	488 (0.54%)
CHD death[2]	261 (0.07%)	3 (0.01%)	17 (0.02%)	86 (0.05%)	155 (0.17%)
Clinical MI	823 (0.21%)	26 (0.05%)	79 (0.11%)	333 (0.20%)	385 (0.43%)
Angina	1577 (0.41%)	68 (0.13%)	152 (0.20%)	714 (0.43%)	643 (0.71%)
CABG/PTCA	1460 (0.38%)	41 (0.08%)	144 (0.19%)	666 (0.40%)	609 (0.67%)
Carotid artery disease	313 (0.08%)	21 (0.04%)	25 (0.03%)	121 (0.07%)	146 (0.16%)
Congestive heart failure	934 (0.24%)	27 (0.05%)	76 (0.10%)	378 (0.23%)	453 (0.50%)
Stroke	779 (0.20%)	19 (0.03%)	60 (0.08%)	296 (0.18%)	404 (0.45%)
PVD	226 (0.06%)	9 (0.02%)	18 (0.02%)	83 (0.05%)	116 (0.13%)
Coronary disease[3]	3171 (0.83%)	118 (0.22%)	294 (0.40%)	1358 (0.82%)	1401 (1.55%)
Total cardiovascular disease	4270 (1.11%)	161 (0.30%)	374 (0.50%)	1774 (1.07%)	1961 (2.17%)
Cancer					
Breast cancer[4]	1999 (0.52%)	205 (0.38%)	362 (0.49%)	915 (0.55%)	517 (0.57%)
Invasive breast cancer	1653 (0.43%)	170 (0.31%)	301 (0.41%)	743 (0.45%)	439 (0.49%)
Non-invasive breast cancer	365 (0.10%)	38 (0.07%)	66 (0.09%)	180 (0.11%)	81 (0.09%)
Ovary cancer	188 (0.05%)	14 (0.03%)	34 (0.05%)	81 (0.05%)	59 (0.07%)
Endometrial cancer[5]	253 (0.11%)	22 (0.07%)	35 (0.08%)	118 (0.12%)	78 (0.15%)
Colorectal cancer	445 (0.12%)	25 (0.05%)	55 (0.07%)	192 (0.12%)	173 (0.19%)
Other cancer[6]	1832 (0.48%)	128 (0.24%)	231 (0.31%)	833 (0.50%)	640 (0.71%)
Total cancer	4605 (1.20%)	389 (0.72%)	702 (0.95%)	2089 (1.27%)	1425 (1.58%)
Fractures					
Hip fracture	388 (0.10%)	9 (0.02%)	33 (0.04%)	127 (0.08%)	219 (0.24%)
Vertebral fracture[7]	50 (0.16%)	2 (0.04%)	5 (0.09%)	15 (0.12%)	28 (0.38%)
Other fracture[6,7]	413 (1.35%)	56 (1.25%)	70 (1.22%)	161 (1.24%)	126 (1.71%)
Total fracture[8]	827 N/A	66 N/A	105 N/A	295 N/A	361 N/A
Deaths					
Cardiovascular deaths	553 (0.14%)	11 (0.02%)	31 (0.04%)	192 (0.12%)	319 (0.35%)
Cancer deaths	923 (0.24%)	51 (0.09%)	108 (0.15%)	392 (0.24%)	372 (0.41%)
Deaths: other known cause	321 (0.08%)	16 (0.03%)	36 (0.05%)	129 (0.08%)	140 (0.16%)
Deaths: unknown cause	150 (0.04%)	8 (0.01%)	10 (0.01%)	57 (0.03%)	75 (0.08%)
Deaths: not yet adjudicated	255 (0.07%)	8 (0.01%)	23 (0.03%)	100 (0.06%)	124 (0.14%)
Total death	2202 (0.57%)	94 (0.17%)	208 (0.28%)	870 (0.53%)	1030 (1.14%)

[1] "CHD" includes clinical MI and CHD death. This definition has changed slightly from the February 2001 report.
[2] "CHD death" includes definite and possible CHD death. This definition has changed slightly from the February 2001 report.
[3] "Coronary disease" includes clinical MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[4] Excludes six cases with borderline malignancy.
[5] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[6] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.
[7] Only women from three bone density clinics are used to compute the annual rates for vertebral and other fractures.
[8] Hip fractures are adjudicated at all clinics, while other fractures are adjudicated only at a few clinics. A combined annualized percentage cannot be computed.

Table 5.7 (Continued)
Locally Verified Outcomes (Annualized Percentages) by Race/Ethnicity for OS Participants

Data as of: August 31, 2001

Outcomes	Ethnicity: American Indian/Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Other/ Unspecified	
Number enrolled	421		2671		7634		3608		78018		1324	
Mean follow-up (months)	45.2		47.6		45.3		41.9		50.0		46.8	
Cardiovascular												
CHD[1]	7	(0.44%)	18	(0.17%)	90	(0.31%)	18	(0.14%)	855	(0.26%)	18	(0.35%)
CHD death[2]	2	(0.13%)	3	(0.03%)	41	(0.14%)	1	(0.01%)	209	(0.06%)	5	(0.10%)
Clinical MI	6	(0.38%)	16	(0.15%)	62	(0.22%)	18	(0.14%)	707	(0.22%)	14	(0.27%)
Angina	9	(0.57%)	30	(0.28%)	131	(0.45%)	36	(0.29%)	1357	(0.42%)	14	(0.27%)
CABG/PTCA	6	(0.38%)	25	(0.24%)	88	(0.31%)	32	(0.25%)	1289	(0.40%)	20	(0.39%)
Carotid artery disease	2	(0.13%)	4	(0.04%)	18	(0.06%)	9	(0.07%)	273	(0.08%)	7	(0.14%)
Congestive heart failure	8	(0.50%)	14	(0.13%)	106	(0.37%)	18	(0.14%)	774	(0.24%)	14	(0.27%)
Stroke	5	(0.32%)	25	(0.24%)	79	(0.27%)	11	(0.09%)	645	(0.20%)	14	(0.27%)
PVD	2	(0.13%)	2	(0.02%)	24	(0.08%)	3	(0.02%)	191	(0.06%)	4	(0.08%)
Coronary disease[3]	18	(1.14%)	54	(0.51%)	285	(0.99%)	64	(0.51%)	2711	(0.83%)	39	(0.75%)
Total cardiovascular disease	25	(1.58%)	81	(0.76%)	392	(1.36%)	82	(0.65%)	3629	(1.12%)	61	(1.18%)
Cancer												
Breast cancer[4]	3	(0.19%)	36	(0.34%)	119	(0.41%)	55	(0.44%)	1767	(0.54%)	19	(0.37%)
Invasive breast cancer	2	(0.13%)	27	(0.25%)	96	(0.33%)	41	(0.33%)	1471	(0.45%)	16	(0.31%)
Non-invasive breast cancer	1	(0.06%)	9	(0.08%)	24	(0.08%)	14	(0.11%)	313	(0.10%)	4	(0.08%)
Ovary cancer	0	(0.00%)	2	(0.02%)	9	(0.03%)	5	(0.04%)	172	(0.05%)	0	(0.00%)
Endometrial cancer[5]	0	(0.00%)	5	(0.07%)	4	(0.03%)	4	(0.06%)	234	(0.12%)	6	(0.20%)
Colorectal cancer	1	(0.06%)	8	(0.08%)	56	(0.19%)	7	(0.06%)	370	(0.11%)	3	(0.06%)
Other cancer[6]	7	(0.44%)	33	(0.31%)	115	(0.40%)	37	(0.29%)	1615	(0.50%)	25	(0.48%)
Total cancer	11	(0.69%)	81	(0.76%)	295	(1.02%)	107	(0.85%)	4059	(1.25%)	52	(1.01%)
Fractures												
Hip fracture	2	(0.13%)	6	(0.06%)	5	(0.02%)	4	(0.03%)	367	(0.11%)	4	(0.08%)
Vertebral fracture[7]	1	(0.25%)	0	(0.00%)	1	(0.03%)	2	(0.10%)	46	(0.19%)	0	(0.00%)
Other fracture[6,7]	6	(1.51%)	2	(1.60%)	22	(0.57%)	19	(0.96%)	361	(1.50%)	3	(1.61%)
Total fracture[8]	9	N/A	8	N/A	27	N/A	24	N/A	752	N/A	7	N/A
Deaths												
Cardiovascular deaths	5	(0.32%)	9	(0.08%)	69	(0.24%)	3	(0.02%)	458	(0.14%)	9	(0.17%)
Cancer deaths	3	(0.19%)	14	(0.13%)	73	(0.25%)	20	(0.16%)	802	(0.25%)	11	(0.21%)
Deaths: other known cause	9	(0.57%)	4	(0.04%)	30	(0.10%)	13	(0.10%)	258	(0.08%)	7	(0.14%)
Deaths: unknown cause	0	(0.00%)	2	(0.02%)	23	(0.08%)	7	(0.06%)	117	(0.04%)	1	(0.02%)
Deaths: not yet adjudicated	2	(0.13%)	11	(0.10%)	29	(0.10%)	9	(0.07%)	202	(0.06%)	2	(0.04%)
Total death	19	(1.20%)	40	(0.38%)	224	(0.78%)	52	(0.41%)	1837	(0.57%)	30	(0.58%)

[1] "CHD" includes clinical MI and CHD death. This definition has changed slightly from the February 2001 report.
[2] "CHD death" includes definite and possible CHD death. This definition has changed slightly from the February 2001 report.
[3] "Coronary disease" includes clinical MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[4] Excludes six cases with borderline malignancy.
[5] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[6] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.
[7] Only women from three bone density clinics are used to compute the annual rates for vertebral and other fractures.
[8] Hip fractures are adjudicated at all clinics, while other fractures are adjudicated only at a few clinics. A combined annualized percentage cannot be computed.

Table 5.8
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for OS Participants who did not report a prevalent condition at baseline

Data as of: August 31, 2001

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	93676	12386	17321	41196	22773
Mean follow-up (months)	49.2	52.6	51.4	48.1	47.6
Hospitalizations					
Ever	26952 (7.02%)	2510 (4.62%)	3862 (5.21%)	11937 (7.23%)	8643 (9.57%)
Two or more	10384 (2.71%)	818 (1.51%)	1272 (1.72%)	4544 (2.75%)	3750 (4.15%)
Other					
DVT[1]	353 (0.10%)	34 (0.06%)	36 (0.05%)	160 (0.10%)	123 (0.14%)
Pulmonary embolism	209 (0.06%)	23 (0.04%)	23 (0.03%)	90 (0.06%)	73 (0.08%)
Diabetes (treated)	2537 (0.69%)	288 (0.54%)	467 (0.65%)	1159 (0.73%)	623 (0.72%)
Gallbladder disease[2]	3211 (0.99%)	513 (1.07%)	627 (0.98%)	1419 (1.03%)	652 (0.88%)
Hysterectomy	1761 (0.78%)	258 (0.80%)	359 (0.78%)	802 (0.84%)	342 (0.68%)
Glaucoma	4185 (1.14%)	415 (0.78%)	632 (0.88%)	1894 (1.20%)	1244 (1.50%)
Osteoporosis	12605 (3.58%)	1186 (2.26%)	1897 (2.69%)	5857 (3.89%)	3665 (4.69%)
Osteoarthritis[3]	9010 (4.03%)	1070 (2.73%)	1569 (3.22%)	4050 (4.39%)	2321 (5.31%)
Rheumatoid arthritis	2573 (0.71%)	373 (0.71%)	508 (0.72%)	1012 (0.65%)	680 (0.80%)
Intestinal polyps	6569 (1.89%)	753 (1.46%)	1191 (1.71%)	3052 (2.06%)	1573 (2.02%)
Lupus	576 (0.15%)	94 (0.17%)	114 (0.15%)	251 (0.15%)	117 (0.13%)
Kidney stones[3]	1103 (0.40%)	145 (0.40%)	211 (0.41%)	461 (0.38%)	286 (0.43%)
Cataracts[3]	14370 (6.15%)	691 (1.88%)	1745 (3.45%)	7459 (7.16%)	4475 (10.60%)
Pills for hypertension	11567 (4.21%)	1279 (2.83%)	2030 (3.51%)	4972 (4.33%)	3286 (5.81%)

Outcomes	Race/Ethnicity: American Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Other/ Unspecified
Number randomized	421	2671	7634	3608	78018	1324
Mean follow-up (months)	45.2	47.6	45.3	41.9	50.0	46.8
Hospitalizations						
Ever	137 (8.64%)	469 (4.43%)	2105 (7.31%)	721 (5.72%)	23187 (7.13%)	333 (6.44%)
Two or more	58 (3.66%)	163 (1.54%)	812 (2.82%)	222 (1.76%)	8994 (2.77%)	135 (2.61%)
Other						
DVT[1]	2 (0.13%)	2 (0.02%)	25 (0.09%)	5 (0.04%)	317 (0.10%)	2 (0.04%)
Pulmonary embolism	1 (0.06%)	3 (0.03%)	18 (0.06%)	1 (0.01%)	185 (0.06%)	1 (0.02%)
Diabetes (treated)	27 (2.00%)	91 (0.90%)	409 (1.62%)	162 (1.38%)	1814 (0.57%)	34 (0.69%)
Gallbladder disease[2]	20 (1.60%)	42 (0.44%)	209 (0.82%)	131 (1.33%)	2767 (1.01%)	42 (0.97%)
Hysterectomy	3 (0.38%)	31 (0.45%)	78 (0.60%)	58 (0.84%)	1560 (0.80%)	31 (1.03%)
Glaucoma	23 (1.59%)	134 (1.33%)	500 (1.89%)	142 (1.19%)	3325 (1.07%)	61 (1.23%)
Osteoporosis	50 (3.43%)	380 (3.92%)	522 (1.90%)	385 (3.32%)	11072 (3.73%)	196 (4.14%)
Osteoarthritis[3]	38 (4.31%)	258 (3.46%)	734 (4.40%)	409 (4.95%)	7434 (3.97%)	137 (4.35%)
Rheumatoid arthritis	21 (1.45%)	55 (0.54%)	397 (1.52%)	224 (1.91%)	1823 (0.59%)	53 (1.10%)
Intestinal polyps	25 (1.72%)	161 (1.70%)	535 (2.02%)	188 (1.59%)	5573 (1.90%)	87 (1.87%)
Lupus	7 (0.45%)	11 (0.10%)	57 (0.20%)	27 (0.22%)	463 (0.14%)	11 (0.21%)
Kidney stones[3]	10 (0.89%)	16 (0.21%)	127 (0.60%)	68 (0.72%)	863 (0.37%)	19 (0.50%)
Cataracts[3]	51 (5.29%)	373 (5.78%)	1033 (5.66%)	446 (5.11%)	12249 (6.24%)	218 (6.83%)
Pills for hypertension	48 (4.79%)	332 (4.45%)	982 (6.97%)	480 (5.08%)	9559 (4.00%)	166 (4.58%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 5.9
First Reported Locally Verified Outcomes Before and After AV-3[1] for OS Participants

Data as of: August 31, 2001

Outcome	Before AV-3	After AV-3
Number at risk	93676	92855
Cardiovascular		
CHD[2]	695	311
CHD death[3]	154	107
Clinical MI	585	238
Angina	1245	332
CABG/PTCA	1062	398
Carotid artery disease	230	83
Congestive heart failure	660	274
Stroke	524	255
PVD	182	44
Coronary disease[4]	2381	790
Total cardiovascular disease	3178	1092
Cancer		
Breast cancer[5]	1478	521
Invasive breast cancer	1208	445
Non-invasive breast cancer	284	81
Ovary cancer	141	47
Endometrial cancer	186	67
Colorectal cancer	321	124
Other cancer[6]	1311	521
Total cancer	3378	1227
Fractures		
Hip fracture	268	120
Vertebral fracture	33	17
Other fracture[6]	271	142
Total fracture	562	265
Deaths		
Cardiovascular deaths	333	220
Cancer deaths	533	390
Deaths: other known cause	193	128
Deaths: unknown cause	68	82
Deaths: not yet adjudicated	83	172
Total death	1210	992

[1] AV-3 date is the blood draw date for participants with an AV-3 blood draw and the OS enrollment date plus 3 years for participants without an AV-3 blood draw.
[2] "CHD" includes clinical MI and CHD death.
[3] "CHD death" includes definite and possible CHD death. This definition has changed slightly from the February 2001 report.
[4] "Coronary disease" includes clinical MI, Evolving Q-wave MI, Possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[5] Excludes eight cases with borderline malignancy.
[6] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

Table 5.10
Counts of Participants with Self-Reported Outcomes Before and After AV-3[1]
for OS Participants who did not report a prevalent condition at baseline

Data as of: August 31, 2001

Outcome	Before AV-3	After AV-3
Number at risk	93676	92855
Ever hospitalized	18737	8215
DVT[2]	222	131
Pulmonary embolism	126	83
Diabetes (treated)	1703	834
Gallbladder disease[3]	2079	1132
Hysterectomy	1226	535
Glaucoma	2702	1483
Osteoporosis	8543	4062
Osteoarthritis[4]	6193	2817
Rheumatoid arthritis	1689	884
Intestinal polyps	4279	2290
Lupus	341	235
Kidney stones[3]	621	482
Cataracts[3]	8887	5483
Pills for hypertension	7955	3612

[1] AV-3 date is the blood draw date for participants with an AV-3 blood draw and the OS enrollment date plus 3 years for participants without an AV-3 blood draw.

[2] Inpatient DVT only.

[3] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

[4] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

6. Outcomes Processing

6.1 Overview

Most outcomes are initially ascertained by self-report on *Form 33 – Medical History Update.* CT participants complete this form every six months; OS participants complete this form every year. Those participants who report an outcome requiring documentation and adjudication are asked to complete a more detailed form (*Form 33D*) that collects the information needed to request the associated medical records.

After these forms are completed and entered into the database, the CCs identify adjudication cases based on the *Form 33D* information. CCs then request hospital and related records. Once the cases are documented, clinic staff sends the charts having potential cardiovascular, cancer, and fracture outcomes to the local physician adjudicator for evaluation and classification. Key cardiovascular outcomes are further adjudicated by a central committee process. The investigators at UCSF (Steve Cummings, PI) subcontract to the CCC to adjudicate all hip fractures. Staff at the CCC code and adjudicate all cancers of major interest in the study (breast, colon, rectum, ovary, and endometrium) using standardized SEER guidelines. Outcomes for selected other diseases, such as diabetes, gallbladder disease, and hysterectomy, are collected as self-reports only.

The monitoring analysis is conducted on outcomes as classified by the local adjudicator. Currently, about 94% of the self-reports have been adjudicated. We do *not* report on the self-reports for which the adjudication process is not yet finished. We feel that we have now reached the stage in the study where the fraction of the self-reports that are not yet adjudicated is sufficiently small that omitting unadjudicated self-reports does not distort the larger picture.

6.2 Terminology

When a particular outcome, say MI, is investigated, all participants can be divided into five groups:

1. Those who have no self-report of an MI and have no locally confirmed MI.

2. Those who have a self-report of an MI and a locally confirmed MI. We refer to these participants' cases as *confirmed (with self-report).*

3. Those who have no self-report of an MI but do have a locally confirmed MI usually as a result of an investigation of a self-report of another outcome. We refer to these participants' cases as *confirmed (without self-report).*

4. Those who have a self-report of an MI but do not have a locally confirmed MI, and for whom all relevant adjudication cases are closed. We refer to these participants' self-reports as *denied.*

5. Those who have a self-report of an MI, but do not have a locally confirmed MI, while some of the relevant adjudication cases are still open. We refer to these participants' self-reports as *open.*

The *confirmed cases* are the cases of participants in categories 2 and 3; the *self-reports* are the cases of participants in categories 2, 4, and 5; the *closed self-reports* are the cases of participants in categories 2 and 4. For some analyses we divide the *denied* self-reports into three groups:

4a. The reports of the participants for which the self-reported outcome was denied, but for whom a related outcome (e.g., an angina based on an MI self-report) was found. We refer to those participants' self-reports as *denied - related outcome found.* For the outcome tables, we consider all cardiovascular outcomes to be related, all cancer outcomes to be related, and all fracture outcomes to be related.

4b. The reports of the participants for which the self-reported outcome was denied after review of the relevant documentation. We refer to those participants' self-reports as *denied - no (related) outcome found.*

4c. The reports of the participants for which the self-report was *denied* for *administrative reasons.* Self-reports can only be denied if they satisfy one of several narrowly defined rules. Usually this means that no documentation was obtained after several attempts over a one-year period.

6.3 Outcomes Data Quality

Tables 6.1-6.2 – Timeliness and Completeness of Local Adjudications display the distribution of time required to locally adjudicate a self-reported outcome by month on *Form 33* for the CT and the OS, respectively. This table is based on the day on which the form was received by the clinic, which may not be the same as the day on which the form was entered in the database. Overall 95% of self-reported outcomes in the CT and 94% of the self-reported outcomes in the OS requiring adjudication have been closed. In particular, 52% of the outcomes in the CT and 55% of the outcomes in the OS have been closed within 90 days of self-report and 72% (CT) and 75% (OS) within 180 days. (Note: the fact that the percentages for the OS appear better is because most of the outcomes in 1996 and earlier, when outcomes processing was considerably slower, are CT outcomes.)

Since 1997, the percentage of forms that were adjudicated within 90 days has increased from about 40% to over 70%, and the percentage of forms that were adjudicated within 180 days has increased from about 60% to almost 90%. At the same time, the percentage of forms that are more than a year old that have not yet been adjudicated has been reduced to 0.7%. Currently, 29 of the 40 clinics have ten or fewer outstanding *Forms 33D* that are more than a year old.

Figures 6.1-6.2 – Timeliness per Period of Self-Report display Kaplan-Meier curves for the time period from reporting an outcome on *Form 33D* until the adjudication case is closed per year of self-report separately for the CT and OS. Both figures clearly show that improvements in the processing of outcomes have happened throughout the study. The CCC continues to work closely with the Outcomes-PMC to develop reports and other tools that will facilitate timely outcomes processing by the CCs. The two current areas of emphasis of the OPMC are assisting clinics in closing out the few really old cases, and assisting the remaining clinics that are lagging behind in the timeliness of outcomes processing.

Tables 6.3-6.4 – Agreement of Local Adjudications with Self-Reports show condition types that the participant can indicate on *Form 33* or *Form 33D* and the fraction of time that the local adjudicator agrees with that self-report. Because of the complications of the adjudication process, it is not straightforward to define an appropriate estimate of the accuracy of individual self-reports. For example, for most outcome types, second occurrences do not need to be adjudicated, but if the participant reports a second occurrence before the first is confirmed, an adjudication case will be opened. This case will be closed without a locally confirmed outcome when the first self-report is confirmed. To circumvent this and similar problems, the unit in *Tables 6.3* and *6.4* is defined to be a *participant* rather than an outcome event. For some participants whose self-report is denied, related outcomes may be found. We also note that on *Form 33* and *Form 33D* participants report a "stroke or transient ischemic attack (TIA)," while for monitoring purposes only the outcome "stroke" is used. Thus, the number of confirmed cases in *Tables 6.3* and *6.4,* which include TIA, is substantially larger than that in some of the outcomes tables in other sections of this report.

A self-reported outcome may be denied for the following reasons: (i) the outcome did take place, but could not be verified because insufficient evidence was available to the WHI adjudicator; (ii) the outcome did not take place, but a related outcome (which may or may not be of interest to WHI) occurred; (iii) the outcome took place before enrollment in WHI; and (iv) the current self-report was a duplicate report of a previous self-report.

The accuracy of self-reports varies considerably by outcome. For many outcomes the agreement rates for the CT are a few percentage points higher than for the OS. The accuracy of cancer and fracture self-reports may be higher than that for cardiovascular disease because more cardiovascular self-reports result in a related outcome. If those related outcomes are included with the confirmed self-reports, cardiovascular outcomes have a 75% agreement rate between self-reports and locally confirmed outcomes (83% if we exclude angina, which is probably the softest cardiovascular outcome), cancer outcomes have an agreement rate of 87% (93% for the primary cancers), and fracture outcomes have an agreement rate of 79% for the CT and OS combined.

Note that the accuracy of self-reports for *other fractures* (*other cancers*) reflects the percentage of people who reported an *other fracture* (*other cancer*) for whom any of the fractures (cancers) in the other category was found, even if the participant indicated the wrong skeletal site (cancer site).

Tables 6.5-6.6 – Agreement of Central Adjudications with Local Adjudications show that there is good agreement between local and central adjudications for all outcomes. Often angina and congestive heart failure occur in conjunction with an MI. Disagreement on angina or CHF, when there is agreement about the MI is not considered very serious. Some self-reports are locally adjudicated as one type of outcome, while they are centrally adjudicated as another outcome. Data regarding such cross-classification is not shown. As of August 31, 2001 the rules as to which locally confirmed cardiovascular cases are centrally adjudicated have changed. The current tables reflect only the period before that data. In particular, from now on stroke for HRT participants will be centrally adjudicated by NHLBI neurologists.

Table 6.7-6.8 – Agreement of Locally and Centrally Adjudicated Cause of Death. We note that in general there is good agreement between the local and central assessment of the cause of

death. For most causes the agreement is about 80-90%. Notable exceptions are the "other" and "unknown" categories of all types: central adjudication seems to be able to determine the cause of death more frequently than local adjudication. In this table artherosclerotic death includes both definite and possible CHD death, as early on in the study these two categories were a combined cause of death.

6.4 Outcomes Data Summary

Table 6.9 – Locally Verified Outcomes (Annualized Percentages) by Age and Ethnicity for CT contains the number of locally verified outcomes for the major WHI outcomes categories. Since about 6% of the self-reports still need to be adjudicated, the numbers in these tables give a lower bound on the number of outcomes that currently have occurred.

Currently, for the CT we observe approximately 95% of the invasive breast cancer, 75% of the colorectal cancer and 35% of the hip fracture, and 60% of the CHD cases of what was assumed for the power calculations. Note that DVT and PE, which are only adjudicated for HRT participants, are not included in this table.

Table 6.10 – Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Ethnicity for CT contains counts of the number of self-reports for some of the WHI outcomes that are not adjudicated. As for many of the confirmed outcomes, the participants over report (see *Tables 6.3-6.4)*. The numbers in these tables should be seen as upper bounds to the number of outcomes that have currently occurred. Not surprisingly, for many of the outcomes the rates differ considerably by minority status and by age at baseline.

Similar tables for the HRT, DM, CaD, and the OS components are in the chapters about these components. Currently, the rate of fractures in the OS and CT is very similar. The rate of cardiovascular events is slightly higher and the rate of cancers is slightly lower in the CT than in the OS.

Tables 6.11 – Locally Confirmed Other Cancers and *6.12 – Locally Confirmed Other Fractures* split out the other cancers and other fractures for the locally verified outcomes by event type and by study. Since for OS participants other fractures are only locally verified at the three bone mineral density clinics, we provide the number of self-reported fractures for these participants. In the CT, approximately 80% of self-reported fractures are confirmed, though the location of the fracture is misreported in approximately 25-30% of cases.

6.5 ECG Data

Electrocardiograms (ECGs) are given to all CT participants at baseline and in years 3, 6, and 9. The ECGs are sent to EPICARE (Pentti Rauthaharju, PI), which subcontracts to the CCC. EPICARE provides the CCC with a comprehensive analysis of each individual ECG, as well as with a serial analysis of the follow-up ECGs of a participant relative to that participant's baseline ECG. This serial analysis is intended to identify silent MIs: MIs that are detected by this ECG analysis, but were not reported by the participant. As of February 28, 2001, the CCC had received serial analysis on 49,554 CT participants whose year 3 ECGs and/or their year 6 ECGs had been analyzed by EPICARE.

Table 6.13 – Cross-tabulation of ECG Codes Suggesting an MI and Locally Confirmed and Self-Reported MI for All CT Participants shows the relation between MIs that have been identified prior to the follow-up ECG and incident MIs as identified by the ECG analysis. A total of 40 evolving Q-wave MIs have been identified. We note that 15 of these MIs were also identified by the regular outcomes reporting process. The remaining 25 evolving Q-wave MIs are thus the "definite silent MIs." *Table 6.9* also gives the number of possible silent MIs.

6.6 Vital Status

Table 6.14 – Cause of Death: CT and OS Participants (Annualized Percentages) presents the cause of death for CT and OS participants. To reduce the time that it takes before cause of death information is available on WHI participants who have passed away, clinics are encouraged to report a "temporary" cause of death for those participants for whom some, but not all, documentation related to the death has been collected. The goal is that a temporary cause is entered in the database as soon as possible, preferably within eight weeks. The cause based on the complete documentation should be entered as soon as all documents are collected. Cases for which reported unsuccessful requests for documentation have been made over a one-year period can be closed out with incomplete documentation.

Since the previous semi-annual report, we have completed the first NDI search. Results of this investigation are reported below and detailed in *Table 6.15*. The NDI search identified 26 women as dead, whose death had not otherwise been ascertained by WHI. The death of an additional 10 participants was also identified by WHI, but their death was not yet adjudicated. For these participants we used the cause of death based on the NDI provided ICD code, in *Table 6.14*.

As of the August 31, 2001 database, there were 1,419 deaths in the CT and 2,202 in the OS. Of the 1,419 CT deaths, there were 1192 (84%) for which a final adjudication (or NDI report) was available, and an additional 116 (8%) for which a temporary adjudication was available. These 1,419 CT deaths include 73 that were first reported after July 1 of this year. Of the 1,346 that were first reported before July 1, 2001, 1,184 have a final adjudication and 98 have a temporary one, giving us cause of death information on 95% of the CT deaths. For the OS there is cause of death information on 88% of all deaths, and 93% of all deaths that were reported before July 1, 2000.

Table 6.15 – Results of NDI Search. Since the last *Semi-Annual Progress Report*, we have carried out our first search of the National Death Index (NDI) database. This search was carried out for the Clinical Trial and the Observational Study combined, and all numbers of participants in this subsection refer to the combined studies. Early this spring we submitted information on 1,252 participants who were reported dead to WHI before January 1, 2000, 2,249 names of participants who were lost-to-follow-up as of August 8, 2000, with whom the last contact was before January 1, 2000, and 500 participants whom we knew to be alive as of January 1, 2000. *Table 6.15* shows the number of matches that NDI returned, and the number of those matches that were of sufficient quality to use in WHI. Briefly, a match was considered to be of sufficient quality if:

1. the date of last contact with the participant is before the date of death reported by NDI; and
2. the gender of the match returned by NDI is female;

3. NDI considers the match to be class 3 or better *or* first name and last name and date of birth match between the NDI record and the WHI record.

If all 9 digits of the social security number match between the NDI record and the WHI record, the match is an NDI class 3 or better. If various other combinations of items match between NDI and WHI the match can be class 2 or 3 as well. For participants known to be dead, we also consider matches where the date of death matches between NDI and WHI, and at most one of gender, first name, last name, or date of birth do not match.

We note that the NDI search identified 53 lost-to-follow-up participants as dead. As it turned out, however, about half of these participants were reported dead to WHI since August 31, 2000. The remaining 26 (8 CT, 18 OS) are included in all relevant tables. For these participants, CCC scientists converted the ICD-9 and ICD-10 codes that were provided by NDI in the death subclasses that we use in WHI.

Table 6.16 – Lost-to-Follow-up and Vital Status by Clinic: CT Participants displays information about the follow-up and vital status by clinic. Since 1999, clinics are regularly provided with a list of participants for whom there is no *Form 33* within the last 18 months and who are not known to be deceased. Clinics are asked to make every effort to try to locate these participants and to encourage further study participation. Some participants had information in the database that indicated that she never wanted to be contacted again by WHI. If this were the case, clinics were to verify whether this participation status was correct. If indeed a participant has expressed this opinion, she is not to be contacted again. For these participants, we will still be able to obtain limited vital status information from National Death Index (NDI) searches.

About 2.1% of the CT participants are deceased, we do not know the vital status of about 1.5% of the CT participants, and 1.9% of the participants request no further follow-up. In addition, we lack recent outcomes information on an additional 0.1% of the participants. The study design assumed that 3% per year of the participants would be lost-to-follow-up or death. As the average follow-up of participants is now 4.7 years, we note that the follow-up is much better than what was assumed in the design.

There is considerable clinic-to-clinic variation in the vital status data. The percentage of participants who are lost-to-follow-up ranges from 0.1 to 8.5% per clinic. The percentage of participants who stopped follow-up ranges from less than 0.3 to 8.2%.

Table 6.17 – Lost-to-Follow-up and Vital Status by Clinic: OS Participants contains the same information as *Table 6.16* but about the OS. For OS, the participants are considered lost-to-follow-up if we have not received a *Form 33* within the last 24 months. Approximately 3.0% of the OS participants are either lost-to-follow-up or have stopped follow-up.

Table 6.1
Timeliness and Completeness of Local Adjudications – CT Participants[1]

Data as of: August 31, 2001

Forms with conditions[2]		Number and % of forms with conditions locally adjudicated by days from Form 33 encounter date to completion of local adjudication							
Date of Form 33 encounter		≤ 90		≤ 180		Closed		Open	
	N	N	%	N	%	N	%	N	%
<= June 30 1996	3916	268	7%	775	20%	3911	100%	5	0%
1996 July - December	1383	308	22%	718	52%	1382	100%	1	0%
1997 January-June	2177	765	35%	1333	61%	2174	100%	3	0%
1997 July-December	2546	977	38%	1514	59%	2546	100%	0	0%
1998 January-June	3576	1664	47%	2783	78%	3576	100%	0	0%
1998 July-December	4159	2362	57%	3337	80%	4151	100%	8	0%
1999 January-June	4602	2834	62%	3810	83%	4584	100%	18	0%
1999 July-December	4466	2872	64%	3700	83%	4439	99%	27	1%
2000 January-June	4708	3107	66%	3969	84%	4615	98%	93	2%
2000 July	653	469	72%	559	86%	640	98%	13	2%
2000 August	850	584	69%	715	84%	816	96%	34	4%
2000 September	674	444	66%	582	86%	650	96%	24	4%
2000 October	854	566	66%	734	86%	813	95%	41	5%
2000 November	747	492	66%	662	89%	707	95%	40	5%
2000 December	627	438	70%	575	92%	600	96%	27	4%
2001 January	896	620	69%	777	87%	818	91%	78	9%
2001 February	801	567	71%	704	88%	713	89%	88	11%
2001 March	982	700	71%	869	88%	870	89%	112	11%
2001 April	770	566	74%	668	87%	668	87%	102	13%
2001 May	920	686	75%	752	82%	752	82%	168	18%
2001 June	818	540	66%	540	66%	540	66%	278	34%
2001 July	826	375	45%	375	45%	375	45%	451	55%
2001 August	622	72	12%	72	12%	72	12%	550	88%
Total	42573	22276	52%	30523	72%	40412	95%	2161	5%

[1] This table is based on the day *Form 33* was received by the clinic, not on the day the form was entered in the database.
[2] Conditions are self-reported events that require additional documentation.

Table 6.2
Timeliness and Completeness of Local Adjudications – OS Participants[1]

Data as of: August 31, 2001

Forms with conditions[2]		Number and % of forms with conditions locally adjudicated by days from Form 33 encounter date to completion of local adjudication							
Date of Form 33 encounter		≤ 90		≤ 180		Closed		Open	
	N	N	%	N	%	N	%	N	%
<= June 30 1996	238	85	36%	128	54%	238	100%	0	0%
1996 July - December	1310	308	24%	702	54%	1307	100%	3	0%
1997 January-June	2153	845	39%	1403	65%	2148	100%	5	0%
1997 July-December	2296	709	31%	1359	59%	2293	100%	3	0%
1998 January-June	2833	1269	45%	2037	72%	2831	100%	2	0%
1998 July-December	3803	2006	53%	2903	76%	3795	100%	8	0%
1999 January-June	4752	2851	60%	3936	83%	4741	100%	11	0%
1999 July-December	4215	2535	60%	3427	81%	4191	99%	24	1%
2000 January-June	5927	3789	64%	4909	83%	5823	98%	104	2%
2000 July	804	524	65%	659	82%	776	97%	28	3%
2000 August	911	620	68%	776	85%	876	96%	35	4%
2000 September	688	451	66%	589	86%	658	96%	30	4%
2000 October	711	467	66%	621	87%	680	96%	31	4%
2000 November	598	370	62%	510	85%	556	93%	42	7%
2000 December	597	413	69%	517	87%	555	93%	42	7%
2001 January	853	615	72%	753	88%	783	92%	70	8%
2001 February	719	506	70%	644	90%	649	90%	70	10%
2001 March	998	633	63%	874	88%	874	88%	124	12%
2001 April	864	596	69%	724	84%	724	84%	140	16%
2001 May	1102	792	72%	873	79%	873	79%	229	21%
2001 June	813	502	62%	502	62%	502	62%	311	38%
2001 July	888	393	44%	393	44%	393	44%	495	56%
2001 August	802	91	11%	91	11%	91	11%	711	89%
Total	38875	21370	55%	29330	75%	36357	94%	2518	6%

[1] This table is based on the day *Form 33* was received by the clinic, not on the day the form was entered in the database.
[2] Conditions are self-reported events that require additional documentation.

Figure 6.1 Clinical Trial Timeliness per Period of Self-Report

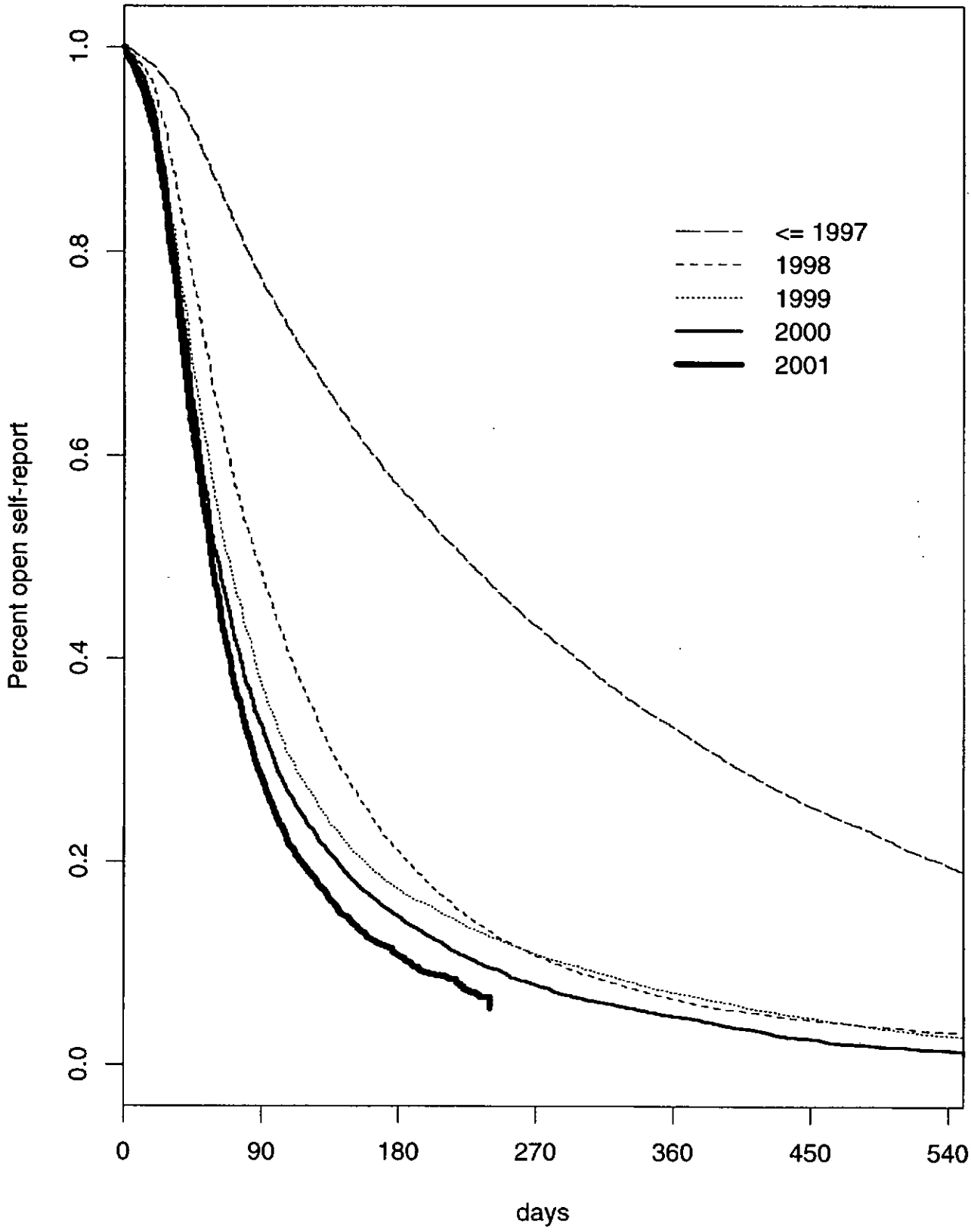


Figure 6.2 Observational Study Timeliness per Period of Self-Report

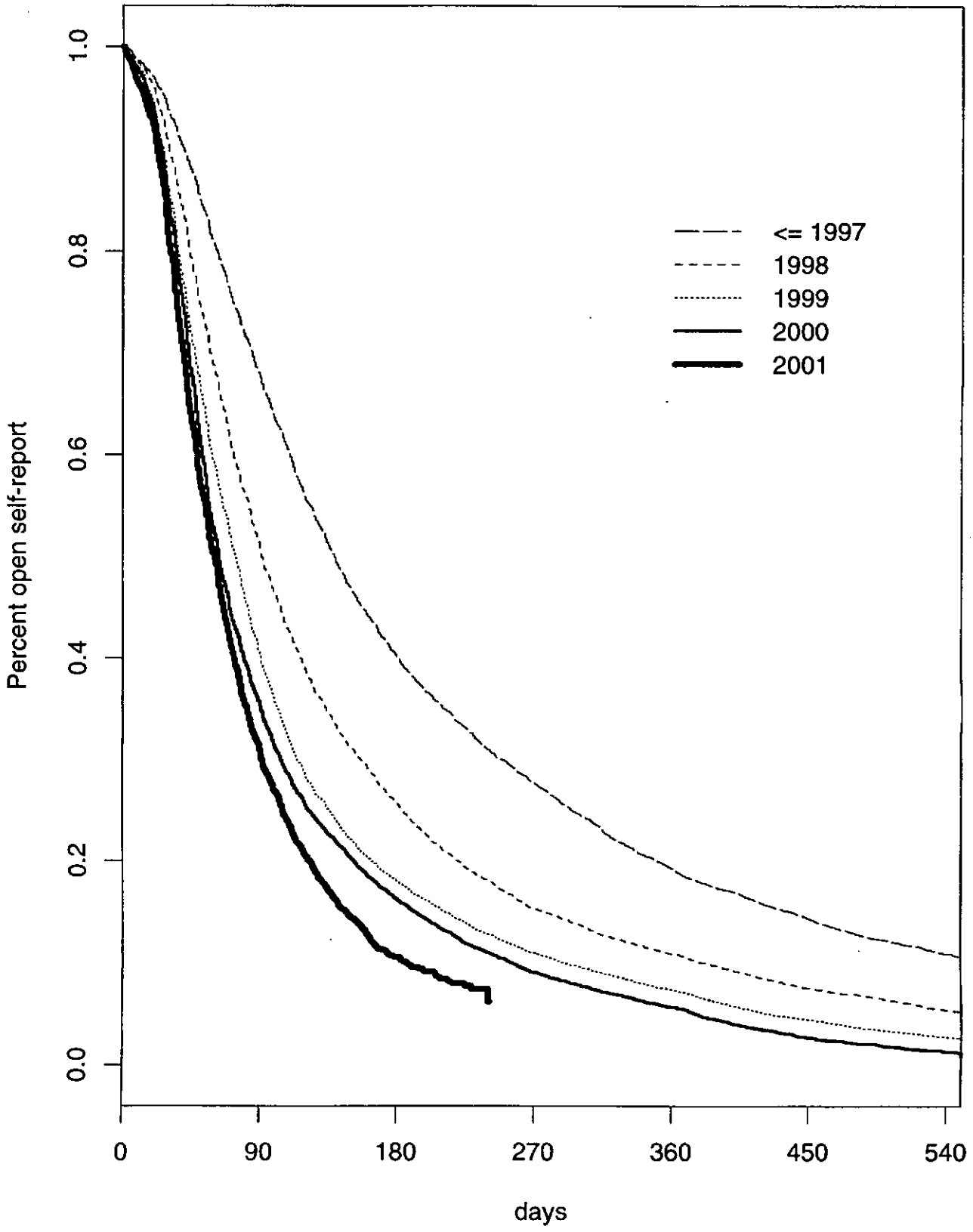


Table 6.3
Agreement of the Local Adjudications with Self-Reports — CT Participants

Data as of: August 31, 2001

	Participants with a self-report	Closed		Confirmed		Denied – related outcome found		Denied – no outcome found		Administrative denials	
		N	%	N	%[1]	N	%[1]	N	%[1]	N	%[1]
Cardiovascular											
MI	773	726	94%	519	(71%)	112	(15%)	86	(12%)	9	(1%)
Angina[2]	1548	1432	93%	676	(47%)	65	(5%)	663	(46%)	28	(2%)
Congestive heart failure	502	462	92%	325	(70%)	30	(6%)	100	(22%)	7	(2%)
CABG/PTCA	1651	1521	92%	1202	(79%)	123	(8%)	174	(11%)	22	(1%)
Carotid artery disease[3]	231	217	94%	179	(82%)	23	(11%)	11	(5%)	4	(2%)
Stroke/TIA[4]	1210	1113	92%	846	(76%)	51	(5%)	198	(18%)	18	(2%)
PVD	164	152	93%	87	(57%)	21	(14%)	41	(27%)	3	(2%)
DVT[5]	238	224	94%	159	(71%)	32	(14%)	28	(13%)	5	(2%)
Pulmonary embolism[5]	118	105	89%	91	(87%)	5	(5%)	9	(9%)	0	(0%)
Cancers											
Breast cancer	1526	1409	92%	1350	(96%)	1	(<1%)	51	(4%)	7	(<1%)
Ovary cancer	154	145	94%	107	(74%)	28	(19%)	7	(5%)	3	(2%)
Endometrial cancer	202	186	92%	142	(76%)	23	(12%)	19	(10%)	2	(1%)
Colorectal	422	389	92%	343	(88%)	20	(5%)	24	(6%)	2	(1%)
Other cancer[6]	1731	1608	93%	1215	(76%)	87	(5%)	275	(17%)	31	(2%)
Fractures											
Hip fracture	332	308	93%	247	(80%)	22	(7%)	35	(11%)	4	(1%)
Vertebral fracture	580	536	92%	278	(52%)	19	(4%)	219	(41%)	20	(4%)
Other fracture	5354	5070	95%	4115	(81%)	44	(1%)	760	(15%)	151	(3%)

[1] Percentages between parentheses are relative to "closed."
[2] Angina that is self-reported after a confirmed MI, is not adjudicated. In particular, 183 such self-reports of angina are excluded from this table.
[3] Carotid artery disease that is self-reported after a confirmed Stroke, is not adjudicated. In particular, 4 such self-reports of Carotid artery disease are excluded from this table.
[4] Stroke and TIA have a combined self-report. Only stroke is monitored. There were 248 participants who reported stroke/TIA for whom only TIA was confirmed.
[5] HRT Participants only.
[6] Excludes non-melanoma skin cancer.

Table 6.4
Agreement of the Local Adjudications with Self-Reports — OS Participants

Data as of: August 31, 2001

	Participants with a self-report	Closed		Confirmed		Denied – related outcome found		Denied – no outcome found		Administrative denials	
		N	%	N	%[1]	N	%[1]	N	%[1]	N	%[1]
Cardiovascular											
MI	736	653	89%	438	(67%)	116	(18%)	87	(13%)	12	(2%)
Angina[2]	1799	1668	93%	731	(44%)	103	(6%)	798	(48%)	36	(2%)
Congestive heart failure	595	536	90%	394	(74%)	36	(7%)	96	(18%)	10	(2%)
CABG/PTCA	1888	1715	91%	1315	(77%)	160	(9%)	209	(12%)	31	(2%)
Carotid artery disease[3]	283	257	91%	205	(80%)	27	(11%)	20	(8%)	5	(2%)
Stroke/TIA[4]	1411	1271	90%	931	(73%)	58	(5%)	251	(20%)	31	(2%)
PVD	221	205	93%	116	(57%)	26	(13%)	58	(28%)	5	(2%)
Cancers											
Breast cancer	2272	2050	90%	1870	(91%)	12	(1%)	140	(7%)	28	(1%)
Ovary cancer	202	187	93%	131	(70%)	28	(15%)	27	(14%)	1	(1%)
Endometrial cancer	252	222	88%	168	(76%)	34	(15%)	16	(7%)	4	(2%)
Colorectal	481	445	93%	376	(84%)	27	(6%)	33	(7%)	9	(2%)
Other cancer[5]	2314	2095	91%	1453	(69%)	151	(7%)	431	(21%)	60	(3%)
Fractures											
Hip fracture	449	398	89%	313	(79%)	2	(1%)	73	(18%)	10	(3%)
Vertebral fracture	74	68	92%	41	(60%)	6	(9%)	17	(25%)	4	(6%)
Other fracture	587	553	94%	403	(73%)	12	(2%)	118	(21%)	20	(4%)

[1] Percentages between parentheses are relative to "closed."
[2] Angina that is self-reported after a confirmed MI, is not adjudicated. In particular, 141 such self-reports of angina are excluded from this table.
[3] Carotid artery disease that is self-reported after a confirmed Stroke, is not adjudicated. In particular, 5 such self-reports of Carotid artery disease are excluded from this table.
[4] Stroke and TIA have a combined self-report. Only stroke is monitored. There were 311 participants who reported stroke/TIA for whom only TIA was confirmed.
[5] Excludes non-melanoma skin cancer.

Table 6.5
Agreement of Central Adjudications with Local Adjudications — CT Participants

Data as of: August 31, 2001

	Locally confirmed N	Centrally adjudicated N	%	In agreement N	%[1]
Cardiovascular					
MI	792	553	70%	467	84%
Angina[2]	1480	1045	71%	789	76%
Congestive heart failure	715	479	67%	363	76%
CABG/PTCA	1302	898	69%	866	96%
DVT[3]	206	141	68%	119	84%
Pulmonary embolism[3]	122	79	65%	70	89%
Cancers					
Breast cancer	1370	1130	82%	1126	100%
Invasive	1075	888	83%	874	98%
Non-Invasive	295	242	82%	208	86%
Ovary cancer	128	105	82%	83	79%
Endometrial cancer	173	154	89%	148	96%
Colorectal cancer	386	308	80%	302	98%
Fractures					
Hip fracture	301	249	83%	239	96%

[1] Percentage is relative to centrally adjudicated cases.
[2]Participants with a confirmed MI no longer require adjudication of angina.
[3]HRT only; DVT and PE are centrally adjudicated since May of 1997.

Table 6.6
Agreement of Central Adjudications with Local Adjudications — OS Participants

Data as of: August 31, 2001

	Locally confirmed N	Centrally adjudicated N	%	In agreement N	%[1]
Cardiovascular					
MI	823	521	63%	423	81%
Angina[2]	1656	1146	69%	897	78%
Congestive heart failure	934	614	66%	486	79%
CABG/PTCA	1460	954	65%	908	95%
Cancers					
Breast cancer	1927	1517	79%	1483	98%
Invasive	1581	1241	78%	1173	95%
Non-Invasive	346	276	80%	222	80%
Ovary cancer	170	123	72%	101	82%
Endometrial cancer	242	195	81%	180	92%
Colorectal cancer	421	317	75%	299	94%
Fractures					
Hip fracture	388	310	80%	303	98%

[1] Percentage is relative to centrally adjudicated cases.
[2] Participants with a confirmed MI no longer require adjudication of angina.

Table 6.7
Agreement of Locally and Centrally Adjudicated Cause of Death for All CT Participants

Data as of: August 31, 2001

	Closed Local[1]	Closed Central N	Closed Central %	Confirmed Cause N	Confirmed Cause %[2]	Related Cause N	Related Cause %[2]	Unrelated Cause N	Unrelated Cause %[2]
Final adjudicated death	1184	771	(65%)	630	(82%)	64	(8%)	77	(10%)
Cardiovascular									
Atherosclerotic cardiac[3]	190	123	(65%)	106	(86%)	7	(6%)	10	(8%)
Cerebrovascular	91	52	(57%)	46	(88%)	1	(2%)	5	(10%)
Pulmonary embolism	6	2	(33%)	1	(50%)	0	(0%)	1	(50%)
Other cardiovascular	75	48	(64%)	22	(46%)	18	(38%)	8	(17%)
Unknown cardiovascular	19	14	(74%)	1	(7%)	6	(43%)	7	(50%)
Total cardiovascular deaths	381	239	(63%)	176	(74%)	32	(13%)	31	(13%)
Cancer									
Breast cancer	17	11	(65%)	11	(100%)	0	(0%)	0	(0%)
Ovarian cancer	39	26	(67%)	24	(92%)	2	(8%)	0	(0%)
Endometrial cancer	5	3	(60%)	2	(67%)	1	(33%)	0	(0%)
Colorectal cancer	61	41	(67%)	36	(88%)	2	(5%)	3	(7%)
Other cancer	427	289	(68%)	271	(94%)	10	(3%)	8	(3%)
Unknown cancer site	29	19	(66%)	11	(58%)	8	(42%)	0	(0%)
Total cancer deaths	578	389	(67%)	355	(91%)	23	(6%)	11	(3%)
Accident/injury									
Homicide	5	4	(80%)	3	(75%)	1	(25%)	0	(0%)
Accident	35	23	(66%)	20	(87%)	1	(4%)	2	(9%)
Suicide	5	5	(100%)	5	(100%)	0	(0%)	0	(0%)
Other injury	3	2	(67%)	0	(0%)	1	(50%)	1	(50%)
Total accidental deaths	48	34	(71%)	28	(82%)	3	(9%)	3	(9%)
Other									
Other known cause	131	82	(63%)	59	(72%)	2	(2%)	21	(26%)
Unknown cause	46	27	(59%)	12	(44%)	4	(15%)	11	(41%)
Total deaths - other causes	177	109	(62%)	71	(65%)	6	(6%)	32	(29%)

[1] Excludes temporary adjudications.
[2] Percentages are relative to closed central.
[3] "Atherosclerotic cardiac" combines definite and possible CHD death.

Table 6.8
Agreement of Locally and Centrally Adjudicated Cause of Death for All OS Participants

Data as of: August 31, 2001

	Closed Local[1]	Closed Central N	Closed Central %	Confirmed Cause N	Confirmed Cause %[2]	Related Cause N	Related Cause %[2]	Unrelated Cause N	Unrelated Cause %[2]
Final adjudicated death	1690	1084	(64%)	869	(80%)	95	(9%)	120	(11%)
Cardiovascular									
Atherosclerotic cardiac[3]	238	138	(58%)	105	(76%)	12	(9%)	21	(15%)
Cerebrovascular	112	75	(67%)	67	(89%)	3	(4%)	5	(7%)
Pulmonary embolism	14	6	(43%)	4	(67%)	0	(0%)	2	(33%)
Other cardiovascular	113	68	(60%)	26	(38%)	28	(41%)	14	(21%)
Unknown cardiovascular	19	16	(84%)	1	(6%)	11	(69%)	4	(25%)
Total cardiovascular deaths	496	303	(61%)	203	(67%)	54	(18%)	46	(15%)
Cancer									
Breast cancer	97	69	(71%)	66	(96%)	3	(4%)	0	(0%)
Ovarian cancer	53	34	(64%)	32	(94%)	0	(0%)	2	(6%)
Endometrial cancer	15	9	(60%)	5	(56%)	4	(44%)	0	(0%)
Colorectal cancer	74	48	(65%)	45	(94%)	0	(0%)	3	(6%)
Other cancer	551	357	(65%)	332	(93%)	13	(4%)	12	(3%)
Unknown cancer site	52	33	(63%)	24	(73%)	8	(24%)	1	(3%)
Total cancer deaths	842	550	(65%)	504	(92%)	28	(5%)	18	(3%)
Accident/injury									
Homicide	4	4	(100%)	4	(100%)	0	(0%)	0	(0%)
Accident	44	33	(75%)	28	(85%)	2	(6%)	3	(9%)
Suicide	14	11	(79%)	9	(82%)	0	(0%)	2	(18%)
Other injury	1	1	(100%)	1	(100%)	0	(0%)	0	(0%)
Total accidental deaths	63	49	(78%)	42	(86%)	2	(4%)	5	(10%)
Other									
Other known cause	226	147	(65%)	107	(73%)	3	(2%)	37	(25%)
Unknown cause	63	35	(56%)	13	(37%)	8	(23%)	14	(40%)
Total deaths - other causes	289	182	(63%)	120	(66%)	11	(6%)	51	(28%)

[1] Excludes temporary adjudications.
[2] Percentages are relative to closed central.
[3] "Atherosclerotic cardiac" combines definite and possible CHD death.

Table 6.9
Locally Verified Outcomes (Annualized Percentages) by Age for CT Participants

Data as of: August 31, 2001

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	68133	9190	14662	31394	12887
Mean follow-up (months)	55.5	61.6	57.7	53.7	52.9
Cardiovascular					
CHD[1]	958 (0.30%)	58 (0.12%)	103 (0.15%)	438 (0.31%)	359 (0.63%)
CHD death[2]	202 (0.06%)	12 (0.03%)	19 (0.03%)	83 (0.06%)	88 (0.15%)
Total MI[3]	821 (0.26%)	48 (0.10%)	89 (0.13%)	378 (0.27%)	306 (0.54%)
Clinical MI	792 (0.25%)	43 (0.09%)	88 (0.12%)	361 (0.26%)	300 (0.53%)
Evolving Q-wave MI[4]	50 (0.02%)	7 (0.01%)	3 (<0.01%)	27 (0.02%)	13 (0.02%)
Possible evolving Q-wave MI[4]	184 (0.06%)	17 (0.04%)	29 (0.04%)	80 (0.06%)	58 (0.10%)
Angina	1401 (0.44%)	67 (0.14%)	181 (0.26%)	679 (0.48%)	474 (0.83%)
CABG/PTCA	1302 (0.41%)	55 (0.12%)	164 (0.23%)	628 (0.45%)	455 (0.80%)
Carotid artery disease	261 (0.08%)	6 (0.01%)	31 (0.04%)	120 (0.09%)	104 (0.18%)
Congestive heart failure	715 (0.23%)	32 (0.07%)	76 (0.11%)	307 (0.22%)	300 (0.53%)
Stroke	720 (0.23%)	26 (0.06%)	67 (0.09%)	323 (0.23%)	304 (0.54%)
PVD	187 (0.06%)	8 (0.02%)	21 (0.03%)	88 (0.06%)	70 (0.12%)
CHD[1]/Possible evolving Q-wave MI	1116 (0.35%)	75 (0.16%)	126 (0.18%)	504 (0.36%)	411 (0.72%)
Coronary disease[5]	2894 (0.92%)	159 (0.34%)	353 (0.50%)	1366 (0.97%)	1016 (1.79%)
Total cardiovascular disease	3826 (1.21%)	193 (0.41%)	443 (0.63%)	1808 (1.29%)	1382 (2.43%)
Cancer					
Breast cancer[6]	1372 (0.44%)	146 (0.31%)	287 (0.41%)	669 (0.48%)	270 (0.48%)
Invasive breast cancer	1078 (0.34%)	106 (0.22%)	230 (0.33%)	523 (0.37%)	219 (0.39%)
Non-invasive breast cancer	307 (0.10%)	40 (0.08%)	62 (0.09%)	152 (0.11%)	53 (0.09%)
Ovary cancer	138 (0.04%)	17 (0.04%)	25 (0.04%)	64 (0.05%)	32 (0.06%)
Endometrial cancer[7]	173 (0.09%)	20 (0.07%)	38 (0.09%)	77 (0.10%)	38 (0.12%)
Colorectal cancer	390 (0.12%)	23 (0.05%)	56 (0.08%)	198 (0.14%)	113 (0.20%)
Other cancer[8]	1432 (0.45%)	116 (0.25%)	224 (0.32%)	695 (0.49%)	397 (0.70%)
Total cancer	3419 (1.09%)	316 (0.67%)	612 (0.87%)	1664 (1.18%)	827 (1.46%)
Fractures					
Hip fracture	301 (0.10%)	10 (0.02%)	19 (0.03%)	112 (0.08%)	160 (0.28%)
Vertebral fracture	332 (0.11%)	14 (0.03%)	33 (0.05%)	136 (0.10%)	149 (0.26%)
Other fracture[8]	4291 (1.36%)	508 (1.08%)	785 (1.11%)	2016 (1.44%)	982 (1.73%)
Total fracture	4779 (1.52%)	527 (1.12%)	829 (1.18%)	2207 (1.57%)	1216 (2.14%)
Deaths					
Cardiovascular deaths	410 (0.13%)	18 (0.04%)	33 (0.05%)	175 (0.12%)	184 (0.32%)
Cancer deaths	630 (0.20%)	37 (0.08%)	75 (0.11%)	311 (0.22%)	207 (0.36%)
Deaths: other known cause	188 (0.06%)	13 (0.03%)	25 (0.04%)	76 (0.05%)	74 (0.13%)
Deaths: unknown cause	191 (0.06%)	13 (0.03%)	17 (0.02%)	90 (0.06%)	71 (0.13%)
Deaths: not yet adjudicated	111 (0.04%)	6 (0.01%)	6 (0.01%)	56 (0.04%)	43 (0.08%)
Total death	1419 (0.45%)	81 (0.17%)	150 (0.21%)	652 (0.46%)	536 (0.94%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death. This definition has changed slightly from the February 2001 report.
[2] "CHD death" includes definite and possible CHD death. This definition has changed slightly from the February 2001 report.
[3] "Total MI" includes clinical MI and evolving Q-wave MI.
[4] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[6] Excludes eight cases with borderline malignancy.
[7] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[8] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

Table 6.9 (Continued)
Locally Verified Outcomes (Annualized Percentages) by Race/Ethnicity for CT Participants

Data as of: August 31, 2001

Outcome	Race/Ethnicity					
	American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Other/ Unspecified
Number randomized	292	1519	6983	2875	55526	938
Mean follow-up (months)	53.8	52.1	54.4	51.8	56.0	51.3
Cardiovascular						
CHD[1]	3 (0.23%)	9 (0.14%)	89 (0.28%)	22 (0.18%)	824 (0.32%)	11 (0.27%)
CHD death[2]	1 (0.08%)	3 (0.05%)	32 (0.10%)	4 (0.03%)	159 (0.06%)	3 (0.07%)
Total MI[3]	2 (0.15%)	8 (0.12%)	68 (0.21%)	19 (0.15%)	714 (0.28%)	10 (0.25%)
Clinical MI	2 (0.15%)	8 (0.12%)	64 (0.20%)	19 (0.15%)	690 (0.27%)	9 (0.22%)
Evolving Q-wave MI[4]	0 (0.00%)	0 (0.00%)	4 (0.01%)	0 (0.00%)	43 (0.02%)	3 (0.07%)
Possible evolving Q-wave MI[4]	1 (0.08%)	4 (0.06%)	22 (0.07%)	4 (0.03%)	151 (0.06%)	2 (0.05%)
Angina	5 (0.38%)	21 (0.32%)	162 (0.51%)	45 (0.36%)	1152 (0.44%)	16 (0.40%)
CABG/PTCA	4 (0.31%)	11 (0.17%)	111 (0.35%)	35 (0.28%)	1130 (0.44%)	11 (0.27%)
Carotid artery disease	3 (0.23%)	4 (0.06%)	20 (0.06%)	1 (0.01%)	231 (0.09%)	2 (0.05%)
Congestive heart failure	2 (0.15%)	5 (0.08%)	110 (0.35%)	17 (0.14%)	571 (0.22%)	10 (0.25%)
Stroke	4 (0.31%)	18 (0.27%)	87 (0.28%)	19 (0.15%)	582 (0.22%)	10 (0.25%)
PVD	2 (0.15%)	0 (0.00%)	32 (0.10%)	3 (0.02%)	148 (0.06%)	2 (0.05%)
CHD[1]/Possible evolving Q-wave MI	4 (0.31%)	13 (0.20%)	108 (0.34%)	26 (0.21%)	952 (0.37%)	13 (0.32%)
Coronary disease[5]	9 (0.69%)	35 (0.53%)	338 (1.07%)	84 (0.68%)	2394 (0.92%)	34 (0.85%)
Total cardiovascular disease	17 (1.30%)	54 (0.82%)	445 (1.41%)	103 (0.83%)	3162 (1.22%)	45 (1.12%)
Cancer						
Breast cancer[6]	2 (0.15%)	30 (0.46%)	91 (0.29%)	30 (0.24%)	1209 (0.47%)	10 (0.25%)
Invasive breast cancer	2 (0.15%)	26 (0.39%)	71 (0.22%)	22 (0.18%)	951 (0.37%)	6 (0.15%)
Non-invasive breast cancer	0 (0.00%)	4 (0.06%)	23 (0.07%)	8 (0.06%)	268 (0.10%)	4 (0.10%)
Ovary cancer	2 (0.15%)	1 (0.02%)	11 (0.03%)	2 (0.02%)	120 (0.05%)	2 (0.05%)
Endometrial cancer[7]	1 (0.17%)	1 (0.02%)	11 (0.08%)	7 (0.10%)	151 (0.10%)	2 (0.09%)
Colorectal cancer	2 (0.15%)	9 (0.14%)	47 (0.15%)	18 (0.14%)	310 (0.12%)	4 (0.10%)
Other cancer[8]	5 (0.38%)	24 (0.36%)	108 (0.34%)	39 (0.31%)	1242 (0.48%)	14 (0.35%)
Total cancer	12 (0.92%)	65 (0.99%)	262 (0.83%)	91 (0.73%)	2961 (1.14%)	28 (0.70%)
Fractures						
Hip fracture	0 (0.00%)	1 (0.02%)	9 (0.03%)	3 (0.02%)	286 (0.11%)	2 (0.05%)
Vertebral fracture	0 (0.00%)	7 (0.11%)	2 (0.01%)	5 (0.04%)	315 (0.12%)	3 (0.07%)
Other fracture[8]	16 (1.22%)	68 (1.03%)	224 (0.71%)	111 (0.89%)	3829 (1.48%)	43 (1.07%)
Total fracture	16 (1.22%)	75 (1.14%)	234 (0.74%)	116 (0.93%)	4291 (1.66%)	47 (1.17%)
Deaths						
Cardiovascular deaths	2 (0.15%)	6 (0.09%)	63 (0.20%)	6 (0.05%)	328 (0.13%)	5 (0.12%)
Cancer deaths	2 (0.15%)	13 (0.20%)	55 (0.17%)	13 (0.10%)	540 (0.21%)	7 (0.17%)
Deaths: other known cause	4 (0.31%)	1 (0.02%)	25 (0.08%)	2 (0.02%)	154 (0.06%)	2 (0.05%)
Deaths: unknown cause	1 (0.08%)	6 (0.09%)	21 (0.07%)	6 (0.05%)	155 (0.06%)	2 (0.05%)
Deaths: not yet adjudicated	0 (0.00%)	6 (0.09%)	11 (0.03%)	5 (0.04%)	88 (0.03%)	1 (0.02%)
Total death	9 (0.69%)	26 (0.39%)	164 (0.52%)	27 (0.22%)	1177 (0.45%)	16 (0.40%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death. This definition has changed slightly from the February 2001 report.
[2] "CHD death" includes definite and possible CHD death. This definition has changed slightly from the February 2001 report.
[3] "Total MI" includes clinical MI and evolving Q-wave MI.
[4] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[6] Excludes eight cases with borderline malignancy.
[7] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[8] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

Table 6.10
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for CT Participants who did not report a prevalent condition at baseline

Data as of: August 31, 2001

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	68133	9190	14662	31394	12887
Mean follow-up (months)	55.5	61.6	57.7	53.7	52.9
Hospitalizations					
Ever	22691 (7.20%)	2270 (4.81%)	3999 (5.67%)	10741 (7.65%)	5681 (10.01%)
Two or more	9606 (3.05%)	841 (1.78%)	1515 (2.15%)	4485 (3.19%)	2765 (4.87%)
Other					
DVT[1]	452 (0.15%)	31 (0.07%)	66 (0.10%)	207 (0.15%)	148 (0.27%)
Pulmonary embolism	248 (0.08%)	14 (0.03%)	38 (0.05%)	118 (0.08%)	78 (0.14%)
Diabetes (treated)	2747 (0.91%)	388 (0.85%)	586 (0.86%)	1242 (0.93%)	531 (0.99%)
Gallbladder disease[2]	3151 (1.20%)	457 (1.10%)	726 (1.20%)	1469 (1.27%)	499 (1.09%)
Hysterectomy	1238 (0.68%)	162 (0.60%)	269 (0.61%)	586 (0.72%)	221 (0.70%)
Glaucoma	4025 (1.33%)	372 (0.80%)	728 (1.06%)	1968 (1.46%)	957 (1.82%)
Osteoporosis	8526 (2.87%)	755 (1.63%)	1390 (2.04%)	4194 (3.18%)	2187 (4.31%)
Osteoarthritis[3]	7820 (5.63%)	1023 (2.98%)	1694 (3.57%)	3627 (4.48%)	1476 (5.23%)
Rheumatoid arthritis	2375 (0.79%)	329 (0.72%)	540 (0.79%)	1042 (0.77%)	464 (0.86%)
Intestinal polyps	5377 (1.84%)	609 (1.33%)	1088 (1.62%)	2687 (2.07%)	993 (1.97%)
Lupus	396 (0.13%)	64 (0.14%)	88 (0.13%)	190 (0.14%)	54 (0.10%)
Kidney stones[3]	901 (0.52%)	116 (0.35%)	191 (0.37%)	429 (0.40%)	165 (0.38%)
Cataracts[3]	12073 (7.73%)	619 (1.83%)	1734 (3.36%)	6644 (6.83%)	3076 (10.06%)
Pills for hypertension	10215 (4.60%)	1283 (3.37%)	2161 (4.02%)	4664 (4.88%)	2107 (6.11%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Other/ Unspecified
Number randomized	292	1519	6983	2875	55526	938
Mean follow-up (months)	53.8	52.1	54.4	51.8	56.0	51.3
Hospitalizations						
Ever	93 (7.10%)	305 (4.63%)	2342 (7.40%)	745 (6.00%)	18939 (7.31%)	267 (6.65%)
Two or more	49 (3.74%)	105 (1.59%)	1016 (3.21%)	283 (2.28%)	8054 (3.11%)	99 (2.47%)
Other						
DVT[1]	2 (0.16%)	1 (0.02%)	41 (0.13%)	8 (0.07%)	397 (0.16%)	3 (0.08%)
Pulmonary embolism	3 (0.23%)	2 (0.03%)	19 (0.06%)	3 (0.02%)	217 (0.08%)	4 (0.10%)
Diabetes (treated)	18 (1.52%)	77 (1.25%)	529 (1.89%)	182 (1.57%)	1903 (0.76%)	38 (1.01%)
Gallbladder disease[2]	15 (1.56%)	52 (0.87%)	255 (0.90%)	135 (1.43%)	2650 (1.23%)	44 (1.29%)
Hysterectomy	4 (0.68%)	19 (0.45%)	72 (0.52%)	34 (0.49%)	1102 (0.71%)	7 (0.30%)
Glaucoma	19 (1.53%)	84 (1.32%)	537 (1.82%)	168 (1.40%)	3168 (1.27%)	49 (1.30%)
Osteoporosis	37 (2.98%)	197 (3.15%)	416 (1.37%)	315 (2.73%)	7440 (3.05%)	121 (3.24%)
Osteoarthritis[3]	41 (0.12%)	171 (0.36%)	790 (0.98%)	396 (1.40%)	6307 (5.55%)	115 (6.66%)
Rheumatoid arthritis	18 (1.53%)	49 (0.77%)	420 (1.43%)	223 (1.88%)	1624 (0.65%)	41 (1.08%)
Intestinal polyps	27 (2.25%)	105 (1.74%)	544 (1.84%)	192 (1.62%)	4438 (1.84%)	71 (1.92%)
Lupus	3 (0.23%)	6 (0.09%)	53 (0.17%)	17 (0.14%)	314 (0.12%)	3 (0.08%)
Kidney stones[3]	6 (0.02%)	23 (0.04%)	86 (0.08%)	54 (0.12%)	721 (0.51%)	11 (0.51%)
Cataracts[3]	53 (0.16%)	243 (0.47%)	1090 (1.12%)	458 (1.50%)	10062 (7.87%)	167 (8.47%)
Pills for hypertension	47 (5.53%)	222 (4.95%)	107 (6.81%)	463 (4.98%)	8282 (4.39%)	123 (4.63%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 6.11
Locally Confirmed Other Cancers: CT and OS Participants

Data as of: August 31, 2001

	CT		OS	
Number of participants	68133		93676	
Mean follow-up time (months)	55.5		49.2	
Ppts with other cancer	1344	(0.43%)	1637	(0.43%)
Accessory sinus	0	(0.00%)	0	(0.00%)
Adrenal gland	2	(<0.01%)	3	(<0.01%)
Anus	5	(<0.01%)	9	(<0.01%)
Biliary tract, parts of (other/unspecified)	18	(0.01%)	12	(<0.01%)
Bladder	78	(0.02%)	102	(0.03%)
Bones/joints/articular cartilage (limbs)	3	(<0.01%)	3	(<0.01%)
Bones/joints/articular cartilage (other)	2	(<0.01%)	2	(<0.01%)
Brain	43	(0.01%)	49	(0.01%)
Cervix	36	(0.01%)	20	(0.01%)
Connective/subcutaneous/soft tissues	6	(<0.01%)	8	(<0.01%)
Endocrine glands, related structures	2	(<0.01%)	1	(<0.01%)
Esophagus	10	(<0.01%)	17	(<0.01%)
Eye and adnexa	3	(<0.01%)	3	(<0.01%)
Genital organs	13	(<0.01%)	8	(<0.01%)
Kidney	65	(0.02%)	81	(0.02%)
Larynx	5	(<0.01%)	4	(<0.01%)
Leukemia	58	(0.02%)	69	(0.02%)
Liver	16	(0.01%)	18	(<0.01%)
Lung	274	(0.09%)	330	(0.09%)
Lymph nodes	7	(<0.01%)	3	(<0.01%)
Lymphoma,Hodgkins	8	(<0.01%)	7	(<0.01%)
Lymphoma,Non-Hodgkins	118	(0.04%)	150	(0.04%)
Melanoma of the skin	172	(0.05%)	231	(0.06%)
Multiple myeloma	57	(0.02%)	44	(0.01%)
Oral (mouth)	8	(<0.01%)	11	(<0.01%)
Palate	3	(<0.01%)	4	(<0.01%)
Pancreas	77	(0.02%)	78	(0.02%)
Parotid gland (Stensen's duct)	2	(<0.01%)	11	(<0.01%)
Peripheral nerves and autonomic nervous system	0	(0.00%)	3	(<0.01%)
Pyriform sinus	0	(0.00%)	0	(0.00%)
Respiratory system, intrathoracic, other	4	(<0.01%)	5	(<0.01%)
Salivary glands, major (other/unspecified)	1	(<0.01%)	4	(<0.01%)
Stomach	14	(<0.01%)	20	(0.01%)
Thyroid	41	(0.01%)	50	(0.01%)
Tongue, part of (other/unspecified)	14	(<0.01%)	7	(<0.01%)
Urinary organs (other/unspecified)	3	(<0.01%)	11	(<0.01%)
Uterus, not otherwise specified	17	(0.01%)	37	(0.01%)
Other/unknown site of cancer	178	(0.06%)	241	(0.06%)

Table 6.12
Locally Confirmed Other Fractures: CT and OS Participants

Data as of: August 31, 2001

	CT		OS[1]	
Locally Confirmed				
Number of participants	68133		6365	
Mean follow-up time (months)	55.5		57.6	
Ppts with other fractures	4294	(1.36%)	408	(1.34%)
Ankle	746	(0.24%)	67	(0.22%)
Carpal bone(s) in wrist	99	(0.03%)	6	(0.02%)
Clavicle or collar bone	67	(0.02%)	8	(0.03%)
Humerus, shaft/unspecified	42	(0.01%)	4	(0.01%)
Humerus, upper end	436	(0.14%)	36	(0.12%)
Humerus, lower end	53	(0.02%)	5	(0.02%)
Metacarpal bone(s)	159	(0.05%)	11	(0.04%)
Patella	185	(0.06%)	18	(0.06%)
Pelvis	138	(0.04%)	19	(0.06%)
Radius or ulna	1214	(0.39%)	120	(0.39%)
Sacrum and coccyx	42	(0.01%)	6	(0.02%)
Scapula	17	(0.01%)	4	(0.01%)
Shaft of femur	53	(0.02%)	4	(0.01%)
Tarsal/metatarsal bones	722	(0.23%)	78	(0.26%)
Tibia and fibula	372	(0.12%)	23	(0.08%)
Tibial plateau	87	(0.03%)	6	(0.02%)
Upper radius/ulna	237	(0.08%)	23	(0.08%)
Unknown other fracture	5	(<0.01%)	0	(0.00%)
Self-Reports				
Number of participants			93676	
Mean follow-up time (months)			49.2	
Elbow			341	(0.09%)
Foot			1307	(0.34%)
Hand			243	(0.06%)
Knee			425	(0.11%)
Lower Arm			1838	(0.48%)
Lower Leg			1484	(0.39%)
Pelvis			282	(0.07%)
Tailbone			90	(0.02%)
Upper Arm			720	(0.19%)
Upper Leg			168	(0.04%)
Vertebra			760	(0.20%)
Other Fracture			1678	(0.44%)

[1] Other fractures for OS Participants are only confirmed in the three bone density clinics.

Table 6.13
Cross-tabulation of ECG Codes Suggesting an Incident MI and Locally Confirmed and Self-Reported MI for All CT Participants

Data as of: August 31, 2001

	No Locally Confirmed MI or Open Self-Report of MI	Open Self-Report of MI[1]	Locally Confirmed MI[2]	Total
All CT Participants				
No significant Q or ST-T evolution[3]	51518	4	284	51806
Borderline Q-wave change[4]	1657	0	39	1696
Ischemic ST-T evolution[5]	989	1	38	1028
Possible evolving Q-wave MI[6]	129[7]	1	17	147
Evolving Q-wave MI[8]	26[9]	0	17	43
Total	54319	6	395	54720
HRT Participants				
No significant Q or ST-T evolution[3]	20500	2	134	20636
Borderline Q-wave change[4]	715	0	16	731
Ischemic ST-T evolution[5]	455	1	14	470
Possible evolving Q-wave MI[6]	59[7]	1	7	67
Evolving Q-wave MI[8]	9[9]	0	10	19
Total	21738	4	181	21923
DM Participants				
No significant Q or ST-T evolution[3]	37102	3	190	37295
Borderline Q-wave change[4]	1147	0	27	1174
Ischemic ST-T evolution[5]	674	0	28	702
Possible evolving Q-wave MI[6]	79[7]	0	15	94
Evolving Q-wave MI[8]	19[9]	0	8	27
Total	39021	3	268	39292
CaD Participants				
No significant Q or ST-T evolution[3]	29337	3	105	29445
Borderline Q-wave change[4]	964	0	14	978
Ischemic ST-T evolution[5]	529	1	11	541
Possible evolving Q-wave MI[6]	76[7]	0	6	82
Evolving Q-wave MI[8]	18[9]	0	7	25
Total	30924	4	143	31071

[1] Includes only self-reports of events before the latest follow-up ECG.
[2] Includes only locally confirmed MIs that took place before the latest follow-up ECG.
[3] Novacode Incident MI code I 5.0
[4] Novacode Incident MI code I 5.7
[5] Novacode Incident MI code I 5.5, I 5.6.1, and I.5.6.2
[6] Novacode Incident MI code I 5.3 and I.5.4
[7] Cases in this cell are the possible evolving Q-wave MIs.
[8] Novacode Incident MI code I 5.1 and I.5.2
[9] Cases in this cell are the evolving Q-wave MIs.

Table 6.14
Cause of Death: CT and OS Participants (Annualized Percentages)

Data as of: August 31, 2001

	CT		OS	
Number Randomized	68133		93676	
Mean Follow-up Time (months)	55.5		49.2	
Total death	1419	(0.45%)	2202	(0.57%)
Adjudicated death	1308	(0.42%)	1947	(0.51%)
Final adjudicated death	1184	(0.38%)	1690	(0.44%)
Temporary adjudicated death	116	(0.04%)	229	(0.06%)
Identified by NDI search	8	(<0.01%)	28	(0.01%)
Cardiovascular				
Atherosclerotic cardiac	203	(0.06%)	261	(0.07%)
CHD deaths adjudicated before 10/99	86	(0.03%)	82	(0.02%)
Definite CHD deaths adjudicated after 10/99	73	(0.02%)	88	(0.02%)
Possible CHD deaths adjudicated after 10/99	44	(0.01%)	91	(0.02%)
Cerebrovascular	96	(0.03%)	127	(0.03%)
Pulmonary embolism	7	(<0.01%)	15	(<0.01%)
Other cardiovascular	81	(0.03%)	123	(0.03%)
Unknown cardiovascular	23	(0.01%)	27	(0.01%)
Total cardiovascular deaths	410	(0.13%)	553	(0.14%)
Cancer				
Breast cancer	19	(0.01%)	109	(0.03%)
Ovarian cancer	41	(0.01%)	59	(0.02%)
Endometrial cancer	6	(<0.01%)	15	(<0.01%)
Colorectal cancer	65	(0.02%)	79	(0.02%)
Other cancer	464	(0.15%)	606	(0.16%)
Unknown cancer site	35	(0.01%)	55	(0.01%)
Total cancer deaths	630	(0.20%)	923	(0.24%)
Accident/injury				
Homicide	5	(<0.01%)	4	(<0.01%)
Accident	36	(0.01%)	46	(0.01%)
Suicide	5	(<0.01%)	14	(<0.01%)
Other injury	3	(<0.01%)	2	(<0.01%)
Total accidental deaths	49	(0.02%)	66	(0.02%)
Other				
Other known cause	139	(0.04%)	255	(0.07%)
Unknown cause	80	(0.03%)	150	(0.04%)
Total deaths – other causes	219	(0.07%)	405	(0.11%)

Table 6.15
Results of NDI Search

Data as of: August 31, 2001

	Known dead[1]		Lost to follow-up[2]		Known alive[3]	
	N	%	N	%	N	%
Submitted to NDI	1252		2249		500	
NDI returned matches	1235	98.6	731	32.5	149	29.8
Matches satisfying WHI criteria	1224	97.8	53	2.4	0	0.0
Reported dead to WHI after 8/31/2000	N/A		27	1.2[4]	N/A	
Only identified using NDI	N/A		26	1.2[5]	N/A	

[1] Participants having a Form 120 or Form 124 with date of death before 1/1/2000.

[2] Participants who were lost-to-follow-up or no-follow-up by 8/31/2000, for whom contact was before 1/1/2000.

[3] Randomly selected participants with whom there was clinic contact after 1/1/2000.

[4] 1 of these participants was a CT participant, 26 were OS participants.

[5] 8 of these participants were CT participants, 18 were OS participants.

Table 6.16
Lost-to-Follow-up and Vital Status by Clinic: CT Participants

Data as of: August 31, 2001

	Deceased		Alive: Current Participation[1]		Alive: Recent Participation[2]		Alive: Past/Unknown Participation[3]		Stopped Follow-up[4]		Lost to Follow-up[5]		Total
	N	%	N	%	N	%	N	%	N	%	N	%	N
Clinic													
Atlanta	35	2.0	1639	95.2	17	1.0	0	0.0	17	1.0	13	0.8	1721
Birmingham	48	2.6	1702	93.1	38	2.1	0	0.0	25	1.4	16	0.9	1829
Bowman	29	1.9	1397	92.1	29	1.9	1	0.1	41	2.7	20	1.3	1517
Brigham	44	1.9	2208	95.7	37	1.6	6	0.3	8	0.3	4	0.2	2307
Buffalo	36	2.2	1546	96.3	9	0.6	0	0.0	11	0.7	4	0.2	1606
Chapel Hill	28	1.8	1474	96.0	1	0.1	0	0.0	32	2.1	1	0.1	1536
Chicago	50	3.1	1492	91.8	10	0.6	1	0.1	49	3.0	24	1.5	1626
Chi-Rush	28	2.1	1205	90.8	28	2.1	2	0.2	30	2.3	34	2.6	1327
Cincinnati	17	1.2	1273	91.3	21	1.5	8	0.6	42	3.0	34	2.4	1395
Columbus	39	2.5	1474	95.0	3	0.2	0	0.0	26	1.7	9	0.6	1551
Detroit	13	0.9	1182	85.8	36	2.6	16	1.2	113	8.2	18	1.3	1378
GWU-DC	27	1.8	1447	95.5	21	1.4	0	0.0	12	0.8	8	0.5	1515
Gainesville	49	2.4	1943	94.2	13	0.6	0	0.0	45	2.2	12	0.6	2062
Honolulu	18	1.3	1320	93.8	18	1.3	0	0.0	39	2.8	13	0.9	1408
Houston	14	1.1	1107	87.0	91	7.2	8	0.6	49	3.9	3	0.2	1272
Iowa City	55	2.3	2333	95.8	15	0.6	0	0.0	14	0.6	18	0.7	2435
Irvine	25	1.5	1477	91.2	31	1.9	3	0.2	37	2.3	47	2.9	1620
L.A.	31	1.8	1570	93.0	41	2.4	0	0.0	27	1.6	19	1.1	1688
La Jolla	49	2.3	1866	86.6	112	5.2	3	0.1	6	0.3	119	5.5	2155
Madison	23	1.5	1501	96.5	6	0.4	0	0.0	17	1.1	8	0.5	1555
Medlantic	47	3.1	1348	90.1	38	2.5	3	0.2	34	2.3	26	1.7	1496
Memphis	52	3.0	1557	89.2	63	3.6	3	0.2	34	1.9	37	2.1	1746
Miami	19	1.3	1148	77.3	148	10.0	1	0.1	43	2.9	126	8.5	1485
Milwaukee	29	1.8	1565	94.7	7	0.4	0	0.0	37	2.2	14	0.8	1652
Minneapolis	42	2.1	1889	94.9	40	2.0	2	0.1	11	0.6	6	0.3	1990
NY-City	34	1.8	1729	91.9	54	2.9	10	0.5	14	0.7	41	2.2	1882
Nevada	41	2.8	1425	95.8	9	0.6	0	0.0	12	0.8	1	0.1	1488
Newark	51	2.1	2187	89.1	117	4.8	0	0.0	75	3.1	24	1.0	2454
Oakland	28	1.8	1512	96.3	5	0.3	0	0.0	14	0.9	11	0.7	1570
Pawtucket	48	1.8	2494	94.3	22	0.8	0	0.0	44	1.7	38	1.4	2646
Pittsburgh	46	2.8	1563	94.6	26	1.6	0	0.0	15	0.9	3	0.2	1653
Portland	37	2.3	1489	91.3	39	2.4	0	0.0	36	2.2	30	1.8	1631
San Antonio	14	1.0	1225	88.3	20	1.4	0	0.0	100	7.2	29	2.1	1388
Seattle	46	2.6	1681	93.4	36	2.0	1	0.1	23	1.3	12	0.7	1799
Stanford	31	1.7	1684	95.0	18	1.0	3	0.2	23	1.3	14	0.8	1773
Stonybrook	27	2.0	1281	94.4	26	1.9	0	0.0	17	1.3	6	0.4	1357
Torrance	22	2.2	895	88.4	38	3.8	1	0.1	32	3.2	24	2.4	1012
Tucson	64	3.1	1855	89.6	29	1.4	0	0.0	36	1.7	87	4.2	2071
U.C. Davis	52	2.7	1751	91.9	45	2.4	1	0.1	15	0.8	41	2.2	1905
Worcester	31	1.9	1555	95.3	22	1.3	1	0.1	8	0.5	15	0.9	1632
Total	1419	2.1	62989	92.5	1379	2.0	74	0.1	1263	1.9	1009	1.5	68133

[1] Participants who have filled in a Form 33 within the last 9 months.
[2] Participants who last filled in a Form 33 between 9 and 18 months ago.
[3] Participants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.
[5] Participants not in any of the above categories.

Table 6.17
Lost-to-Follow-up and Vital Status by Clinic: OS Participants

Data as of: August 31, 2001

	Deceased		Alive: Current Participation[1]		Alive: Recent Participation[2]		Alive: Past/Unknown Participation[3]		Stopped Follow-up[4]		Lost to Follow-up[5]		Total
	N	%	N	%	N	%	N	%	N	%	N	%	N
Clinic													
Atlanta	52	2.1	2282	92.6	108	4.4	0	0.0	13	0.5	9	0.4	2464
Birmingham	79	3.1	2121	83.9	236	9.3	1	0.0	47	1.9	44	1.7	2528
Bowman	50	2.2	1988	89.3	110	4.9	4	0.2	29	1.3	46	2.1	2227
Brigham	31	1.1	2769	94.0	129	4.4	11	0.4	2	0.1	4	0.1	2946
Buffalo	86	3.8	2104	93.6	38	1.7	1	0.0	11	0.5	8	0.4	2248
Chapel Hill	42	2.0	2015	96.7	13	0.6	0	0.0	11	0.5	2	0.1	2083
Chicago	45	2.4	1741	92.2	29	1.5	3	0.2	11	0.6	60	3.2	1889
Chi-Rush	53	2.6	1856	90.6	46	2.2	2	0.1	45	2.2	47	2.3	2049
Cincinnati	45	2.0	1975	87.8	81	3.6	25	1.1	33	1.5	91	4.0	2250
Columbus	42	1.9	2043	92.0	115	5.2	3	0.1	6	0.3	12	0.5	2221
Detroit	33	1.6	1687	79.9	227	10.7	14	0.7	50	2.4	101	4.8	2112
GWU-DC	58	2.6	2149	95.6	32	1.4	1	0.0	1	0.0	6	0.3	2247
Gainesville	60	2.1	2621	93.9	38	1.4	2	0.1	50	1.8	20	0.7	2791
Honolulu	34	1.6	1979	93.7	23	1.1	1	0.0	62	2.9	14	0.7	2113
Houston	53	2.5	1922	90.3	81	3.8	2	0.1	62	2.9	8	0.4	2128
Iowa City	53	1.7	2976	95.4	36	1.2	0	0.0	20	0.6	35	1.1	3120
Irvine	47	2.1	2074	93.0	28	1.3	3	0.1	36	1.6	42	1.9	2230
L.A.	33	1.5	1984	90.4	149	6.8	0	0.0	18	0.8	11	0.5	2195
La Jolla	87	2.5	2898	83.7	223	6.4	34	1.0	28	0.8	194	5.6	3464
Madison	50	2.5	1909	96.4	11	0.6	0	0.0	8	0.4	3	0.2	1981
Medlantic	52	2.4	1911	87.1	142	6.5	7	0.3	5	0.2	76	3.5	2193
Memphis	61	2.4	2193	87.2	178	7.1	0	0.0	63	2.5	21	0.8	2516
Miami	28	2.0	990	72.1	176	12.8	2	0.1	22	1.6	156	11.4	1374
Milwaukee	45	2.0	2058	91.6	86	3.8	0	0.0	17	0.8	41	1.8	2247
Minneapolis	53	1.9	2385	87.5	255	9.4	0	0.0	20	0.7	14	0.5	2727
NY-City	67	2.3	2583	89.0	111	3.8	11	0.4	25	0.9	106	3.7	2903
Nevada	100	4.6	2023	93.1	36	1.7	0	0.0	13	0.6	2	0.1	2174
Newark	63	1.9	2906	86.2	273	8.1	0	0.0	36	1.1	95	2.8	3373
Oakland	59	2.9	1928	93.9	38	1.9	0	0.0	22	1.1	6	0.3	2053
Pawtucket	80	2.2	3082	85.9	319	8.9	48	1.3	27	0.8	32	0.9	3588
Pittsburgh	65	3.4	1659	86.5	128	6.7	2	0.1	28	1.5	35	1.8	1917
Portland	42	1.9	2056	92.1	69	3.1	1	0.0	43	1.9	21	0.9	2232
San Antonio	40	2.1	1725	88.8	51	2.6	1	0.1	100	5.1	25	1.3	1942
Seattle	60	3.6	1521	91.5	41	2.5	7	0.4	11	0.7	22	1.3	1662
Stanford	73	2.7	2444	91.5	100	3.7	2	0.1	44	1.6	7	0.3	2670
Stonybrook	39	1.9	1759	86.7	187	9.2	2	0.1	9	0.4	32	1.6	2028
Torrance	38	2.5	1300	86.5	49	3.3	16	1.1	31	2.1	69	4.6	1503
Tucson	92	3.3	2260	81.3	258	9.3	1	0.0	35	1.3	134	4.8	2780
U.C. Davis	66	2.9	2088	92.0	71	3.1	7	0.3	7	0.3	30	1.3	2269
Worcester	46	2.1	2074	92.6	79	3.5	4	0.2	14	0.6	22	1.0	2239
Total	2202	2.4	84038	89.7	4400	4.7	218	0.2	1115	1.2	1703	1.8	93676

[1] Participants who have filled in a Form 33 within the last 15 months.
[2] Participants who last filled in a Form 33 between 15 and 24 months ago.
[3] Participants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.
[5] Participants not in any of the above categories.

7. Laboratory Studies

7.1 Overview

Blood samples are collected on all CT participants at baseline and year 1 and on a 6% subsample of participants at years 3, 6, and 9. Blood samples are collected on all OS participants at baseline and year 3. All blood samples are obtained in the fasting state (at least 12 hours), maintained at 4° C until plasma or serum is separated. In addition, urine samples are collected on both CT and OS participants at the three Bone Density sites at baseline, year 1 and year 9 for CT and year 3 for OS participants. Plasma, serum, RBC, buffy coat, urine aliquots are then frozen at -70° C and sent on dry ice to the central repository (McKesson Biological Services, Rockville, MD) where storage at -70° C is maintained.

7.2 Status of Analyses

Core Analytes

The analyses of the twenty core analytes are done by Medical Research Laboratories, Highland Heights, Kentucky (MRL). Samples were pulled in pairs (baseline and year 1) and shipped on dry ice in monthly batches to MRL for analysis in a blinded fashion. MRL completed the majority of analyses of baseline and Year 1 blood samples on the 6% subsample of CT participants. See *Sections 2.5* and *3.3* in this report for presentation of the results for HRT and DM. In early 2001, blood aliquot discrepancies between reports from the CCs and McKesson were reviewed and resolved, and a final shipment of baseline and/or year 1 aliquots was sent to MRL for analyses. Results of these final baseline and year 1 analyses are expected later this year.

MRL has also completed the analyses of the 1% OS Measurement Precision Study (OS-MPS) participants. See *Section 5.3* in the Feb. 1, 1999 to August 25, 1999 Semi-Annual Progress Report for the results.

Two shipments of year 3 blood samples collected from the CT 6% subsample participants were sent to MRL this year and results are expected by the end of the year. A final shipment of the year 3 6% subsample specimens will be made in 2002.

DNA Extraction

DNA extraction for WHI is done by BioServe Biotechnologies, Laurel, MD. For each buffy coat sample, BioServe prepares up to four daughter aliquots containing 3 micrograms DNA each and divides the remaining DNA into parent aliquots containing up to 200 micrograms DNA each, depending on the quantity of DNA extracted. BioServe sends the extracted DNA aliquots to McKesson for storage and/or distribution to DNA testing laboratories.

CVD Biomarker Case-Control Study of CHD, Stroke, and VTE in the HRT Clinical Trial

This study is divided into two phases, with phase I including all locally adjudicated cases of CHD, stroke, and VTE occurring within two years of randomization and phase II including similar types of cases occurring more than two years after randomization. The University of Leiden was contracted to perform the DNA testing for the study. All phase I and phase II DNA samples were sent to Leiden, and results from all but the phase II VTE samples have been received, with these final results expected by the end of the year. The University of Vermont was contracted to perform the thrombosis analyses for the study and MRL will perform the lipid analyses. The phase I

samples will be sent to Vermont and MRL in early fall this year and the phase II samples will be sent by the end of the year. Results from both Vermont and MRL are expected by April 2002.

Hormones

Esoterix (Calabasas Hills, CA; formerly Endocrine Sciences) was contracted to perform hormone analyses for WHI. Analyses is on going for the approved paper "Correlates of endogenous sex hormone concentrations in WHI". A total of 300 DM participants, excluding those in the 6% blood subsample, are included in the study. Baseline and year 1 samples for 60 participants were sent to Esoterix earlier this year and results were received. Samples from the remaining 240 participants will be sent in monthly batches of 30 participants during over the next year.

Vitamin D

Blood levels of Vitamin D were analyzed for a sample of CaD intervention and control women. Some results were reported in the February 2001 semi-annual report under CaD, page 4-3.

Ancillary Studies

Analyses of blood samples for two ancillary studies began this past year: ancillary study #83, Paul Ridker, Thrombotic, Inflammatory, and Genetic Markers for Coronary Heart Disease in Postmenopausal Women: A WHI Umbrella Study, and ancillary study #110, Kathryn Rexrode, Sex Steroid Hormones and Risk of Coronary Heart Disease: A nested Case Control Study.

Table 8.1
Performance Monitoring Committee Report
Data as of 8/31/01
DM

	Adjusted C-I[1]				Task Completeness Form 60 - FFQ[4]		% Stopped[5]	
	Average[2]		Sep 00 - Aug 01[3]		Dec 00 - May 01		Cum Aug 01	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Nevada	13.0	1	11.6	1	93.8	1	3.2	1
Oakland	11.7	1	11.0	1	97.5	1	1.9	1
Iowa City	11.4	1	9.5	1	96.6	1	1.2	1
Madison	11.2	1	9.5	1	94.6	1	2.5	1
Columbus	11.1	1	9.7	1	93.9	1	3.9	2
Stanford	11.1	1	10.1	1	93.2	2	3.4	2
Milwaukee	10.8	1	10.0	1	93.2	1	4.3	2
Pittsburgh	10.8	1	9.0	2	96.5	1	1.5	1
Seattle	10.7	1	8.7	2	88.8	3	3.6	2
Minneapolis	10.7	1	8.7	2	90.3	2	3.0	1
GWU-DC	10.6	2	9.2	1	88.3	3	3.4	1
Irvine	10.2	2	8.6	2	90.1	2	5.2	2
Portland	9.9	2	8.0	2	86.7	3	5.3	2
Chicago	9.8	2	9.4	1	90.7	2	9.7	4
Gainesville	9.7	2	8.1	2	91.8	2	5.5	3
Worcester	9.5	2	7.3	3	90.1	2	4.8	2
Torrance	9.4	2	7.7	3	72.4	4	8.6	4
Chapel Hill	9.3	2	8.3	2	93.3	1	2.1	1
UC Davis	9.3	2	9.2	1	88.8	2	5.8	3
LA	9.3	2	7.2	3	88.4	3	5.9	3
Brigham	9.0	3	7.5	3	90.2	2	3.4	2
Buffalo	8.9	3	7.8	3	93.7	1	2.9	1
Pawtucket	8.9	3	7.6	3	90.9	2	5.7	3
Tucson	8.7	3	7.8	3	89.1	2	6.4	3
Memphis	8.7	3	6.5	4	78.8	4	7.1	3
Houston	8.7	3	7.7	3	93.3	1	5.2	2
Bowman	8.6	3	8.1	2	85.2	3	6.5	3
Newark	8.5	3	6.6	4	78.5	4	7.4	4
Stony Brook	8.4	3	6.4	4	83.4	4	4.5	2
Chi-Rush	8.3	3	8.2	2	86.0	3	7.3	4
Cincinnati	8.3	4	6.9	3	88.5	3	9.8	4
Honolulu	8.2	4	6.7	3	86.9	3	6.6	3
Atlanta	8.1	4	6.6	4	86.2	3	2.2	1
LaJolla	7.8	4	6.2	4	81.4	4	5.9	3
NYC	7.7	4	8.3	2	83.9	3	7.3	4
Detroit	7.4	4	5.8	4	74.3	4	12.9	4
Birmingham	6.8	4	5.9	4	82.2	4	6.1	3
San Antonio	6.2	4	4.4	4	80.7	4	15.0	4
Medlantic	5.9	4	5.1	4	83.6	4	7.7	4
Miami	5.1	4	5.3	4	75.9	4	17.0	4
CC Average	**9.2**		**7.9**		**88.0**		**5.7**	

[1] Adjusted C-I defined as (C-I of collected FFQs) x (FFQ completion rate)
[2] Based on FFQs collected after randomization through AV7.
[3] Based on FFQs collected in the last 12 months
[4] From *WHIP 1445-Task Completeness*; complete if encounter date on *Form 60* is -6/+12 months from visit target date, using 6 month period ending 3 months before the data as of date; excludes deaths
[5] From *WHIP CCC0751- DM Intervention & F/U Status*, includes stopped intervention, stopped F/U, and lost-to-F/U; excludes deaths

Table 8.2
Performance Monitoring Committee Report
Data as of 8/31/01
HRT

	Adherence Summary > 80%				Task Completeness Dec 00 - May 01				% Stopped[5]	
	Average[1]		Sep 00 - Aug 01[2]		Form 10[3]		Form 85[4]		Cum Aug 01	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Oakland	80.2	1	77.9	1	97.8	1	94.5	1	19.0	1
Iowa City	75.2	1	69.0	1	97.9	1	96.9	1	24.0	1
Stanford	70.5	1	65.5	1	97.8	1	80.5	4	27.8	1
Minneapolis	69.9	1	65.5	1	96.1	2	94.6	1	26.6	1
Brigham	68.4	1	64.5	1	98.7	1	90.7	2	30.1	1
Cincinnati	68.1	1	64.6	1	95.1	3	91.7	2	31.1	2
Milwaukee	68.0	1	59.5	2	96.8	2	92.3	1	26.7	1
Madison	67.9	1	61.6	1	96.8	2	94.5	1	32.8	2
Portland	67.6	1	61.5	1	92.0	4	87.2	3	24.6	1
Chapel Hill	67.4	1	58.4	2	99.0	1	93.5	1	30.6	2
Gainesville	67.4	2	63.2	1	97.9	1	94.6	1	38.2	4
LA	66.2	2	55.6	3	88.2	4	88.0	3	26.3	1
Pittsburgh	65.9	2	58.2	2	93.8	3	92.8	1	31.0	2
Nevada	64.9	2	61.7	1	99.2	1	92.0	2	30.7	2
Pawtucket	64.1	2	60.6	2	99.0	1	91.5	2	35.3	3
Chicago	62.9	2	60.5	2	99.0	1	90.2	2	32.9	2
Worcester	62.7	2	59.2	2	95.9	2	93.4	1	35.3	3
Birmingham	61.7	2	57.1	2	95.1	3	89.4	2	33.7	2
Torrance	61.1	2	55.4	3	97.0	2	83.5	3	36.4	3
Honolulu	61.0	2	56.0	2	92.6	3	91.2	2	27.4	1
UC Davis	60.2	3	55.5	3	96.6	2	91.4	2	34.6	3
Columbus	59.7	3	56.8	2	98.6	1	93.8	1	34.6	3
Seattle	59.5	3	55.7	2	95.8	2	82.5	4	36.1	3
Newark	59.1	3	51.6	3	90.2	4	90.6	2	30.2	1
Memphis	57.9	3	53.6	3	92.1	4	86.1	3	36.2	3
GWU-DC	57.8	3	52.5	3	95.2	3	77.2	4	34.1	2
Stony Brook	57.8	3	50.2	4	96.7	2	89.3	2	39.7	4
Chi-Rush	57.2	3	51.9	3	93.2	3	86.4	3	37.5	3
Buffalo	56.2	3	52.9	3	96.3	2	88.7	3	37.2	3
Irvine	56.0	3	51.3	4	93.5	3	81.1	4	33.9	2
LaJolla	55.2	4	51.5	3	91.1	4	79.8	4	30.7	2
Atlanta	54.1	4	52.7	3	95.0	3	87.7	3	39.9	4
Bowman	53.6	4	47.3	4	93.1	3	86.3	3	38.0	3
Tucson	53.3	4	50.1	4	93.1	3	85.4	3	41.5	4
San Antonio	53.3	4	50.6	4	92.0	4	78.4	4	41.4	4
NYC	53.1	4	50.3	4	92.5	4	83.1	3	42.4	4
Houston	51.2	4	42.9	4	79.1	4	77.3	4	47.6	4
Detroit	51.0	4	46.2	4	82.3	4	70.6	4	41.4	4
Medlantic	46.9	4	45.4	4	95.8	2	79.1	4	38.0	3
Miami	34.3	4	33.4	4	81.6	4	73.5	4	57.6	4
CC Average	**61.5**		**56.8**		**94.7**		**88.0**		**33.8**	

[1] Adherence from randomization through 1) 12 months before data as of date 2) last adherence collection within the last 12 months before the data as of date, or 3) death; women off intervention are considered non-adherent

[2] Adherence in previous 12 months; excludes deaths; women off intervention are considered non-adherent

[3] From *WHIP 1445-Task Completeness*, complete if encounter date on *Form 10 - HRT Management and Safety* is -3/+3 months from target date

[4] From *WHIP 1445-Task Completeness*, complete if mammogram date on *Form 85 - Mammogram* date is -12/+6 months from AV target date

[5] From *WHIP CCC750-HRT Intervention & F/U Status*; includes stopped intervention, stopped F/U, and lost-to-F/U; excludes deaths

Table 8.3
Performance Monitoring Committee Report
Data as of 8/31/01

CaD

	Adherence Summary > 80%				Task Completeness Form 17[3]		% Stopped[4]	
	Average[1]		Sep 00 - Aug 01[2]		Dec 00 - May 01		Cum Aug 01	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Oakland	80.6	1	84.2	1	97.9	2	7.8	1
Iowa City	73.2	1	74.5	1	97.7	2	11.9	1
Stanford	72.3	1	74.0	1	98.0	1	16.5	1
Minneapolis	68.7	1	70.4	1	96.3	2	13.2	1
Columbus	68.6	1	68.0	1	99.2	1	18.2	2
Nevada	68.0	1	71.5	1	99.7	1	14.7	1
Gainesville	67.8	1	68.4	1	98.3	1	23.5	3
Chi-Rush	63.6	1	62.8	2	94.9	3	24.4	4
Pawtucket	63.4	1	65.8	1	99.2	1	21.6	3
Brigham	63.3	1	64.0	1	97.9	1	20.9	3
Pittsburgh	63.1	2	63.9	2	94.0	3	19.0	2
Honolulu	62.9	2	63.2	2	95.1	3	22.4	3
Chapel Hill	62.8	2	62.8	2	98.8	1	14.0	1
Milwaukee	62.1	2	60.6	3	98.0	1	15.9	1
Portland	61.0	2	61.6	2	94.1	3	18.9	2
Madison	60.2	2	60.5	3	97.9	2	17.9	2
Worcester	59.1	2	62.9	2	97.8	2	15.8	1
Cincinnati	58.9	2	63.8	2	95.8	3	22.0	3
LA	58.7	2	59.5	3	91.6	4	19.9	2
GWU-DC	58.0	2	59.7	3	96.3	2	19.3	2
Seattle	57.6	3	59.3	3	94.8	3	22.8	3
Torrance	57.6	3	63.2	2	93.1	4	20.1	2
Bowman	57.2	3	63.3	2	94.7	3	19.8	2
Buffalo	57.2	3	64.1	1	98.0	1	17.4	1
UC Davis	55.9	3	60.2	3	94.1	3	20.6	3
LaJolla	55.5	3	57.0	3	91.9	4	18.7	2
Stony Brook	54.7	3	52.3	4	97.3	2	24.1	4
Birmingham	54.4	3	61.1	2	96.8	2	15.3	1
San Antonio	53.2	3	56.1	4	96.2	2	24.7	4
Atlanta	52.8	3	60.6	3	93.8	4	23.4	3
Tucson	52.7	4	59.9	3	95.6	3	29.2	4
Chicago	52.6	4	56.3	3	98.4	1	25.0	4
Irvine	51.7	4	52.3	4	93.7	4	22.7	3
NYC	50.7	4	54.7	4	95.2	3	25.2	4
Memphis	49.7	4	53.6	4	92.6	4	29.4	4
Houston	49.6	4	48.3	4	84.4	4	26.2	4
Detroit	47.7	4	48.1	4	85.7	4	28.9	4
Newark	46.4	4	50.5	4	90.6	4	21.6	3
Medlantic	46.2	4	49.9	4	97.5	2	18.6	2
Miami	32.5	4	40.3	4	76.5	4	39.8	4
CC Average	**58.8**	[redacted]	**61.3**	[redacted]	**95.4**	[redacted]	**20.4**	[redacted]

[1] Adherence from randomization through 1) 12 months before data as of date 2) last adherence collection within the last 12 months before the data as of date, or 3) death; women off intervention are considered non-adherent

[2] Adherence in previous 12 months; excludes deaths; women off intervention are considered non-adherent

[3] From *WHIP 1445-Task Completeness*, complete if encounter date on *Form 17 - CaD Management and Safety* is -3/+3 months from target date

[4] From *WHIP CCC753-CaD Intervention & F/U Status*; includes stopped intervention, stopped F/U, and lost-to-F/U; excludes deaths

Table 8.4
Performance Monitoring Committee Report
Data as of 8/31/01

OS

	Task Completeness - Year 3[1] May 00 - Oct 00[2]				% Stopped[3]	
	Form 100		Form 143		Cum Aug 01	
	%	Quartile	%	Quartile	%	Quartile
Nevada	94.2	1	95.6	1	0.7	1
UC Davis	93.5	1	93.2	2	1.6	2
Oakland	92.5	1	95.7	1	1.3	1
Madison	92.0	1	97.6	1	0.6	1
Buffalo	91.0	1	96.2	1	0.9	1
GWU-DC	89.8	1	94.9	1	0.3	1
Iowa City	89.6	1	95.7	1	1.8	2
Brigham	87.0	1	91.4	2	0.2	1
Bowman	86.5	1	90.0	2	3.6	3
Honolulu	86.2	1	90.2	2	3.6	3
Chapel Hill	84.8	2	97.8	1	0.6	1
Portland	84.6	2	94.0	1	3.1	3
Gainesville	84.2	2	93.5	1	2.6	2
Stanford	83.7	2	92.4	2	1.9	2
Birmingham	82.6	2	84.4	3	3.7	3
LA	82.3	2	90.9	2	1.3	1
NYC	82.2	2	89.1	3	4.6	4
Minneapolis	81.5	2	97.1	1	1.3	1
Worcester	81.4	2	89.3	3	1.6	2
Chicago	82.2	2	90.6	2	3.9	3
Columbus	81.2	3	87.6	3	0.8	1
Seattle	80.8	3	80.8	4	2.0	2
Houston	80.6	3	91.8	2	3.3	3
Pittsburgh	79.5	3	84.6	3	4.2	4
Milwaukee	79.1	3	81.4	3	2.6	2
Cincinnati	77.1	3	83.5	3	6.5	4
LaJolla	76.8	3	78.5	4	6.6	4
Stony Brook	76.2	3	83.8	3	2.3	2
Pawtucket	75.9	3	90.8	2	1.7	2
Torrance	74.9	3	81.3	4	6.7	4
Chi-Rush	64.4	4	76.5	4	4.9	4
Newark	74.3	4	81.2	4	4.0	3
Medlantic	73.1	4	81.7	3	3.9	3
San Antonio	72.8	4	88.2	3	6.5	4
Tucson	71.3	4	77.9	4	6.2	4
Atlanta	70.3	4	93.4	2	0.9	1
Irvine	65.2	4	76.4	4	3.6	3
Memphis	62.5	4	72.1	4	3.4	3
Detroit	60.1	4	70.4	4	7.3	4
Miami	46.3	4	60.7	4	13.1	4
CC Average	**79.6**		**87.1**		**3.1**	

[1] From *WHIP1445-Task Completeness;* complete if encounter date is -3/+15 months from AV3 target date

[2] 6-month period ending 10 months before data as of date to allow for 10 month lag in completeness

[3] From *WHIP CCC752 Intervention & F/U Status*; includes stopped F/U, and lost-to-F/U; excludes deaths

Table 8.5
Performance Monitoring Committee Report
Data as of 8/31/01

Outcomes

	Task Completeness						Closed Cases < 14 weeks[4]	
	CT Form 33[1] Dec-May 01		OS Form 33[2] May 00-Oct 00		Form 33D[3] Cum Aug 01		Cum Aug 01	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Nevada	98.2	1	99.0	1	99.7	1	62.9	3
Chapel Hill	97.8	1	99.3	1	100.0	1	73.6	1
Buffalo	97.6	1	96.1	2	99.9	1	84.8	1
Iowa City	97.0	1	95.5	2	99.5	2	75.0	1
Oakland	96.8	1	97.2	1	99.7	2	41.9	4
Columbus	96.6	1	96.4	1	97.7	4	66.3	2
GWU-DC	96.0	1	97.8	1	99.6	2	70.9	2
Brigham	96.0	1	94.1	3	99.3	3	51.5	3
Madison	95.9	1	98.9	1	99.0	3	87.2	1
Gainesville	95.9	1	97.3	1	99.3	3	77.4	1
Stanford	95.9	2	96.7	1	99.2	3	78.7	1
Pittsburgh	95.6	2	94.1	3	99.9	1	66.7	2
Pawtucket	95.4	2	95.2	2	99.2	3	69.4	2
Milwaukee	95.3	2	95.8	2	96.5	4	68.0	2
Minneapolis	95.0	2	98.2	1	97.7	4	64.9	2
Worcester	95.0	2	96.1	2	99.9	1	72.5	1
Stony Brook	94.8	2	95.4	2	99.7	1	80.6	1
Birmingham	94.0	2	89.3	4	99.7	2	34.5	4
Chicago	94.0	2	93.2	3	98.1	4	49.2	3
Seattle	93.2	2	89.8	4	99.6	2	73.8	1
Honolulu	93.1	3	96.3	2	99.4	3	64.8	2
Atlanta	92.6	3	94.4	3	99.3	3	61.8	3
Bowman	91.7	3	90.5	4	99.4	3	29.0	4
Portland	91.6	3	96.0	2	99.9	1	62.3	3
NYC	91.2	3	92.0	3	99.5	2	48.3	4
Medlantic	90.9	3	88.4	4	99.9	1	49.9	3
UC Davis	90.8	3	96.4	2	99.6	2	81.7	1
Irvine	90.7	3	93.4	3	97.2	4	43.6	4
Chi-Rush	90.5	3	90.8	4	99.7	1	66.2	2
Memphis	90.2	3	94.8	3	98.4	4	58.6	3
Tucson	90.0	4	92.0	3	99.6	2	65.3	2
LA	89.3	4	97.1	1	99.1	3	38.1	4
Cincinnati	88.5	4	89.8	4	98.5	4	40.0	4
San Antonio	88.4	4	94.3	3	99.7	2	63.3	2
LaJolla	87.8	4	87.0	4	98.8	4	62.1	3
Newark	87.5	4	91.1	3	99.3	3	62.5	3
Houston	85.1	4	95.2	2	97.4	4	51.9	3
Torrance	85.1	4	88.7	4	99.7	2	29.5	4
Detroit	80.0	4	85.8	4	99.8	1	39.3	4
Miami	72.0	4	80.4	4	93.0	4	47.0	4
CC Average	**92.3**		**93.9**		**99.1**		**63.1**	

[1] From *WHIP 1445-Task Completeness;* complete if encounter date is -3/+3 months from target date

[2] From *WHIP 1445-Task Completeness;* complete if encounter date is -2/+10 months from AV1,4+ target date, -2/+9 from AV2, and -3/+15 for AV3

[3] From *WHIP 1257-Timeliness of Medical History Update Collection*; includes both CT and OS

[4] From *WHIP 1262-Timeliness of Outcomes Processing*; time from receipt of *Form 33, 33D, or 120* to close date

9. Other Study Activities

A number of WHI-related scientific endeavors have been initiated by study investigators. Publications in scholarly journals are approved through the Presentations and Publications Advisory Committee and the Project Office. Ancillary studies are approved by the Design and Analysis Advisory Committee and the Project Office. Those initiatives that could potentially threaten the integrity of the Clinical Trial results before the completion of the study are to be referred to the DSMB for review. A full statement of the relevant policies may be found in the *WHI Manuals, Vol. 1 – Study Protocol and Policies, Section 3 – Study Policies.*

Table 9.1 – Publications presents current and proposed publications that have been approved by the Publications and Presentations Committee.

Table 9.2 – Ancillary Studies lists all ancillary study proposals received by the Design and Analysis Committee along with some key features of the studies and their current status.

These tables represent the current information available to the relevant committees. Updates are clearly needed. Status reports for either papers or ancillary studies may be sent to the CCC, attention Sundara Murphy. The CCC requests one reprint from each published manuscript for study archives.

Table 9.1
Publications

MS ID	Title	Authors	Data Focus	Stage	Reference
1	Informed Consent in the Women's Health Initiative Clinical Trial and Observational Study	**McTiernan**, Rossouw, Manson, Franzi, Taylor, Carleton, Johnson, Nevitt	Gen.	11	Journal of Women's Health 4(5):519-29, 1995
4	The Women's Health Initiative: Overview of the Nutrition Component	**Tinker**, Burrows, Henry, Patterson, Van Horn, Rupp	Gen.	11	Nutrition and Women's Health, pp. 510-542, 1996.
5	Women Health Initiative: Why Now? What is it? What's New?	**Matthews**, Shumaker, Bowen, Langer, Hunt, Kaplan, Klesges, Ritenbaugh	Gen.	11	American Psychologist. 52(2):101-116, 1997 Feb.
6	Low-fat Diet Practices of Older Women: "Prevalence and Implication for Dietary Assessment"	**Patterson**, Kristal, Coates, Ritenbaugh, Van Horn, Caggiula, Snetselaar, Tylavsky	Gen.	11	Journal of the American Dietetic Association. 96(7):670-9, 1996 Jul.
7	The Evolution of the Women's Health Initiative: Perspectives from the NIH	**Rossouw**, Finnegan, Harlan, Pinn, Clifford, McGowan	Gen.	11	Journal of the American Medical Women's Association. 50(2):50-5, 1995 Mar-Apr
8	Design of the WHI Clinical Trial and Observational Study	**Prentice**, Rossouw, Furberg, Johnson, Henderson, Cummings, Manson, Freedman, Oberman, Kuller, Anderson	Gen.	11	Controlled Clinical Trials 19:61-109, 1998
9	Approaches to Monitoring the Results of Long-term Disease Prevention Trials: Examples from the Women's Health Initiative	**Freedman**, Anderson, Kipnis, Prentice, Wang, Rossouw, Wittes, DeMets	CT	11	Controlled Clinical Trials. 17(6):509-25, 1996 Dec.
11	The Role of Randomized Controlled Trials in Assessing the Benefits and Risks of Long-term Hormone Replacement Therapy: Example of the Women's Health Initiative	**Prentice**, Rossouw, Johnson, Freedman, McTiernan	CT	11	Menopause 3(2):71-76, 1996
12	Factors Associated with Insurance Status among Participants in the WHI	**Hsia**, Sofaer, Kieffe, Zapka, Bowen, Mason, Limacher, Pettinger, Lillington	Gen.	11	Journal of Women's Health & Gender-Based Medicine 9(8):881-889, 2000
21	Hypertension and It's Treatment in Postmenopausal Women: Baseline Data from the Women's Health Initiative	**Wassertheil-Smoller**, Anderson, Psaty, Black, Manson, Wong, Francis, Grimm, Kotchen, Langer, Lasser	OS	11	Hypertension 2000;36:780-89
24	Estimation of the Correlation between Nutrient Intake Measures Under Restricted Sampling	**Wang**, Anderson, Prentice	Gen.	11	Biometrics, in press
27	The Effects of Insurance Coverage and Ethnicity on Mammography Utilization in a Postmenopausal Population	**Bush**, Langer	Gen.	11	Western Journal of Medicine 168:236-40, 1998

MS ID	Title	Authors	Data Focus	Stage	Reference
35	Measurement Characteristics of the WHI Food Frequency Questionnaire	**Patterson**, Kristal, Carter, Tinker, Bolton, Agurs-Collins	Gen.	11	Annals of Epidemiology 1999:9:178-197
37	Depression as Mediated by Social Support, Life Events, and Sexual Activity in Postmenopausal Non-Hispanic White and Latina Women	**Larisch**, Talavera, Langer, Velasquez, Elder	Gen.	11	
40	The Health Impact of Domestic Violence in Older Women	**Mouton**, Furniss, Lasser, Rovi	OS	11	Journal of Women's Health & Gender-Based Medicine 1999:8(9):1173-1179
59	Risk Factors for Kidney Stones in Postmenopausal Women in the Southern United States	**Hall**, Pettinger, Oberman, Watts, Johnson, Paskett, Limacher, Hays	Gen.	11	Am J Med Sci 2001;322 (1):1-7
60	WHIMS: a Trial of the Effect of Estrogen Therapy in Preventing and Slowing the Progression of Dementia	**Shumaker**, Bowen	WHIMS	11	Controlled Clinical Trials 19:604-621
63	Health Insurance as a Determinant of Cancer Screening in WHI OS Participants	**Hsia**, Kemper, Kiefe, Zapka, Sofaer, Pettinger, Bowen, Limacher, Lillington, Mason	OS	11	Preventive Medicine 2000;31:261-270
69	Correlates of Serum Lypocene in Older Women	**Casso**, White, Patterson, Agurs-Collins, Kooperberg, Haines	CT	11	Nutrition and Cancer 2000:36:163-69.
70	Correlates of Serum Alpha- and Gamma-Tocopherol in the WHI	**White**, Masaki, Chen, Shikany, Caan, Mares-Perlman, Wilson, Kristal	CT	11	Annals of Epidemiology 2001;11:136-144
71	The Women's Health Initiative: Goals, Rationale, and Current Status	**Liu**	Gen.	11	Menopausal Medicine, Vol.6(2), p.1-4, 1998
88	Estimating Normal Hemogram Values for Postmenopausal Women	**Assaf**, Carleton, Miller, Coccio	Gen.	11	Clinical Journal of Women's Health Vol. 1, No. 1, December 2000, 23-28
103	The Women's Health Initiative: Recruitment Complete - Looking Back and Looking Forward (Guest Editorial)	**Rossouw**, Hurd	CT	11	Journal of Women's Health 8:3-5, 1999.
104	Promoting Adherence and Retention to Clinical Trials in Special Populations: A Women's Health Initiative Workshop	**Wilcox**, Shumaker, Bowen, Naughton, Rosal, Ludlam, Dugan, Hunt, Stevens	Gen.	11	Controlled Clinical Trials, 22 (3), 279-289
108	Cross-Sectional Geometry and Bone Mass in the Proximal Femur in African-American and White Postmenopausal Women	**Nelson**, Hendrix	CT	11	
10	A Comprehensive Data Management System for Multicenter Studies	**Anderson**, Davis, Koch	Gen.	10	

MS ID	Title	Authors	Data Focus	Stage	Reference
17	Sexual Orientation and Health: Comparisons in the Women's Health Initiative Sample	**Valanis**, Bowen, Bassford, Whitlock, Charney, Carter	CT	10	
19	Ethnic, Socioeconomic, and Lifestyle Correlates of Obesity in Women	**Manson**, Lewis, Kotchen, Allen, Johnson, Stefanick, Foreyt, Klesges, Tinker, Noonan, Perri, Hall	Gen.	10	
30	Completeness of Purchase Mailing Lists for Identifying Older Women	**Falkner**, Wactawski-Wende, Trevisan	CT	10	
61	WHI Halfway Paper (100K Paper)	**Langer**, Kotchen, Daugherty, Lewis, Elmer, Trevisan, Noonan, Hendrix, Adams-Campbell	Gen.	10	
72	Post-Menopausal Bone Loss and its Relationship to Oral Bone Loss	**Jeffcoat**, Lewis, Reddy, Wang, Redford	Gen.	10	Periodontics
76	Labeling as a Predictor of Dietary Maintenance	**Hopkins**, Burrows, Bowen, Tinker	CT	10	
86	The Effects of Physical and Emotional Status on Adherence to a Low-fat Dietary Pattern in the Women's Health Initiative	**Tinker**, Perri, Bowen, Patterson, Parker, Wodarski, McIntosh, Sevick	CT	10	
91	Compliance with National Cholesterol Education Program Dietary and Lifestyle Guidelines Among Older Women with Self-reported Hypercholesterolemia: The Women's Health Initiative	**Hsia**, Rodabough, Rosal, Cochrane, Howard, Snetselaar, Frishman, Stefanick	OS	10	
93	Fat Intake in Husbands of Women in the Dietary Component of the Women's Health Initiative	**Shikany**	Gen.	10	
142	Coronary Artery Calcification in African-American and White Women	**Khurana**, Rosenbaum, Howard, Adams-Campbell, Detrano, Hsia	OS	10	
26	Special Populations Recruitment for the WHI: Success and Limitations	**Fouad**, Corbie-Smith, Curb, Howard, Mouton, Simon, Talavera, Thompson, Wang, White, Young	Gen.	9	
43	Sleep Complaints of Postmenopausal Women	**Kripke**, Freeman, Masaki, Brunner, Jackson, Hendrix, Carter	CT	9	
55	Factor Structure and Factor Invariance of the Women's Health Initiative Insomnia Rating Scale	**Levine**, Shumaker, Naughton, Kaplan, Kripke, Bowen	Gen.	9	
67	Association of Yogurt Consumption to Breast and Colorectal Cancers Among WHI Participants in the OS	**Mossavar-Rahmani**, Garland, Caan, Hebert, Wodarski, Vitolins, Himes, Parker	OS	9	

MS ID	Title	Authors	Data Focus	Stage	Reference
73	Innovative Strategies for Monitoring and Enhancing Clinic Performance in the WHI Clinical Trial: The Creation of the Performance Monitoring Committee	**Pottern**, Naughton, Lund, Cochrane, Brinson, Kotchen, McTiernan, Shumaker	Gen.	9	
85	Women's Health Initiative: Rationale, Design and Progress Report	**Johnson**, Anderson, Barad, Stefanick, McNagny	CT	9	
105	Retention of Low Income and Minority Women in Clinical Trials: A Focus Group Study	**Johnson**, Williams, Fouad	CT	9	
109	NCI Monograph: Approaches to Research Trials Recruitment in Hispanic Communities: Review and Recommendations	**Larkey**	Gen.	9	
111	Effects of Fat Intake on Fat Hedonics: Cognition or Taste?	**Bowen**, Green, Vizenor, Vu, Kreuter, Rolls	OS	9	
112	Results of an Adjunct Dietary Intervention Program in the Women's Health Initiative	**Bowen**, Ehret, Pedersen, Snetselaar, Johnson, Tinker, Hollinger, Lichty, Sivertsen, Ocken, Staats, Beedoe	OS	9	
120	Obesity, Body Size, and Risk of Postmenopausal Breast Cancer: The Women's Health Initiative	**Morimoto**, White, McTiernan, Chlebowski, Hays, Stefanick, Margolis, Manson, Kuller, Chen, Muti, Lopez	OS	9	
122	Does Statin Use Reduce Risk of Osteoporotic Fracture or Improve Bone Density in Postmenopausal Women? Results from the Women's Health Initiative Observational Study	**LaCroix**, Cauley, Pettinger, Hsia, Bauer, McGowan, Chen, Lewis, McNeeley, Pasaro, Jackson	OS	9	
126	Influences on Older Women's Adherence to a Low-Fat Diet in the Women's Health Initiative	**Kearney**, Rosal, Ockene, Churchill	CT	9	
135	Radiographic Measurements, Bone Mineral Density and the Singh Index in the Proximal Femur of White and African-American Postmenopausal Women	**Barondess**, Singh, Hendrix, Nelson	OS	9	
149	Health Status of Postmenopausal White Women with Back and Leg Pain Living in the Community: A Pilot Study	**Vogt**, Lauerman, Chirumbole, Kuller	OS	9	
16	Caloric Requirements and Dietary Self-report	**Hebert**, Patterson, Gorfine, St. Jeor, Chlebowski	Gen.	8	
34	The Relationship between Smoking Status, Body Weight, and Waist-to-Hip Ratio: the WHI	**Johnson**, Klesges, Hays, Noonan, Black, Curb, Liu, Manson	Gen.	8	
39	Hormone Replacement Therapy and Dietary Fat Intake Influence on Blood Lipids and Insulin in Postmenopausal Women	**Chlebowski**, Sparks, Stefanick, Howard, Mossavar-Rahmani, McTiernan	Gen.	8	

MS ID	Title	Authors	Data Focus	Stage	Reference
62	Self-reported Urogential Symptoms in Postmenopausal Women: The Women's Health Initiative	**Pastore**, Carter, Hulka, Wells	Gen.	8	
84	Research Staff Turnover and Participant Adherence in the WHI	**Jackson**, Berman, Snetselaar, Granek, Boe, Huber, Milas, Spivak, Chlebowski	CT	8	
99	Risk Factor Clustering in the Insulin Resistance Syndrome and its Relationship to Cardiovascular Disease In White, Black, Hispanic, and Asian Postmenopausal Women	**Howard**, Criqui, Curb, Rodabough, Safford, Santoro, Wilson, Wylie-Rosette	OS	8	
100	The Yield of Six-Month Recall Mammography on Screening Mammograms	**Yasmeen**, Romano, Pettinger, Chlebowski, Lane, Robbins, Hendrix	Gen.	8	
22	Prevalence of Pelvic Organ Prolapse and Urinary Incontinence in Women	**Hendrix**, Harris, Varner, Chang, Barnabei, Mattox, McTiernan, Francis, Nygaard	CT	7	
29	Effects of Diet Intervention on Motivation to make other Health Related Changes	**Langer**, Lo	CT	7	
57	Regional Differences in Stroke Morbidity at Baseline in the WHI	**Johnson**, Hall, Oberman, Sheps, Hulka, Hays, Baum, Schenkėn, Burke, Limacher, Anderson, Jeppson	Gen.	7	
79	Databased Tracking and Statistical Models of the Clinical Trial Recruitment Process	**Creech**	CT	7	
98	Patterns of Antioxidant Supplement Use in Participants in the Women's Health Initiative	**Shikany**, Patterson, Dunn, Anderson, Agurs-Collins	Gen.	7	
115	Prevalence and 3-year Incidence of Domestic Violence in Older Women	**Mouton**, Hunt, Brzyski, Rodabough	OS	7	
31	Comparisons between Never Smokers, Former Smokers, and Current Smokers in the WHI	**Hymowitz**, Ockene, Bowen, Robbins, Brunner, Shikany, Wagenknecht	OS	6	
53	Dietary, Physical Activity, and Exercise Patterns Among Diabetics	**Agurs-Collins**, Adams-Campbell, Pasaro, Howard	Gen.	6	
78	Association Between Antioxidants and BMD in an Ethnically Diverse Population of Older Women	**Wolf**, Cauley, Stone, Nevitt, Simon, Jackson, LaCroix, Lewis, Wactawski-Wende, LeBoff	Gen.	6	
81	The Prevalence of Urinary Incontinence in WHI Women	**Hendrix**, Clark, Ling, Dugan, Salmieri, Hurtado, McNeeley, Laube, McTiernan, Francis	Gen.	6	

MS ID	Title	Authors	Data Focus	Stage	Reference
107	Physical Activity Throughout the Life Course: The Women's Health Initiative	**Evenson**, Wilcox, Heiss, King, Daugherty, McTiernan	OS	6	
113	Prior Use of Oral Contraceptives and Fracture Risk in Menopausal Women	**Barad**, Kooperberg, Wactawski-Wende, Hendrix, Watts, Liu	Gen.	6	
134	Creative Self-Monitoring Tools in the Dietary Modification Component of the Women's Heath Initiative	**Mossavar-Rahmani**, Henry, Bragg, Brewer, Freed, Kinzel, Pederson, Soule, Vosburg	CT	6	
13	Cardiovascular and other Physiological Correlates of Depression	**Wassertheil-Smoller**, Campbell, Shumaker, Ockene, Robbins, Dunbar, Greenland, Cochrane, Noonan	Gen.	5	
25	Hormone Replacement Therapy Effects on the Resting ECG	**Greenland**, Daugherty, Frishman, Kadish, Limacher, Schwartz	CT	5	
36	Prevalence of Silent MI	**Sagar**, Kotchen, Wong, Graettinger, Burke, Van Vorhees, McIntosh	CT	5	
38	The Relationship of Selected Dietary Components and Risk of Adenoma and Colorectal Cancer among Postmenopausal Women: WHI	**Frank**, Agurs-Collins, Gams, Garland, Khandekar, Paskett, Wylie-Rosette, Pettinger	Gen.	5	
41	Determinants of Fasting Hyperinsulinemia	**Manson**, LaCroix, Haan, Rodrigues, Wagenknecht, Johnson, Allen, Hendrix	Gen.	5	
44	Effect of Hysterectomy with Ovarian Reservation on Cardiovascular Morbidity and Mortality	**Brzyski**, Barnabei, Barad, Guidice, Satterfield, Margolis, McNeeley	CT	5	
49	Patterns of Use and Characteristics Associated with HRT among Postmenopausal Women	**Dunn**, Greenland, Woods, Stovall, Bartholow, Francis	Gen.	5	
51	The Relationship of Quality of Social Support to Frequency of Cancer Screening Behaviors among Postmenopausal Women	**Lane**, Taylor, Glanz, Elam, Klaskala, Powell, Messina, Smith	Gen.	5	
52	Nutrient Intake of Women with Diabetes in the WHI Observational Study Cohort	**Tinker**, Gams, Lee, Smith, West, Snetselaar, Caggiula	Gen.	5	
66	Physical Activity and CVD in Women: the Role of Moderate vs. Vigorous Exercise	**Manson**, Mouton, LaCroix, Greenland, Oberman, Perri, Siscovick, Sheps	OS	5	
74	Baseline Characteristics of the WHI-OS Breast Cancer Survivor Cohort	**Paskett**, Sherman, Andersen, Hays, McDonald, Naughton	OS	5	
83	Physical Activity and Risk of Breast Cancer in Postmenopausal Women: the Women's Health Initiative	**McTiernan**, Wilcox, Coates, Woods, Ockene, Adams-Campbell, White, Kooperberg	Gen.	5	

MS ID	Title	Authors	Data Focus	Stage	Reference
87	Incidence and Correlates of Hip and Knee Replacement in the WHI	**Wallace**, White, Chang, Nevitt, LaCroix, Kaplan, Sturm	Gen.	5	
92	Comparison of Self-report, Discharge Diagnosis, and Adjudication of Cardiovascular Events in the WHI	**Heckbert**, Hsia, Kooperberg, McTiernan, Curb, Barbour, Gaziano, Safford, Psaty, Frishman	Gen.	5	
95	The Effects of Becoming a Widow on Health Behaviors and Health Status in Postmenopausal Women: The Women's Health Initiative	**Wilcox**, Evenson, Wassertheil-Smoller, Mouton, Loevinger, Cochrane	OS	5	
102	Cardiovascular and Mortality Outcomes Related to Anti-Hypertensive Drug Therapy in the WHI	**Wassertheil-Smoller**, Margolis, Mouton, Trevisan, Oberman, Greenland, Kotchen, Psaty, Anderson, Black, Hilkert	OS	5	
106	Utility of Body Mass Index (BMI) as a Proxy for Obesity Among White, Black, Asian, Native American and Hispanic Post-menopausal Women	**Going**, Chen, Tinker, Stefanick, St. Jeor, Lewis	Gen.	5	
132	The Association of Non-Melanoma Skin Cancer and a Second Malignancy	**Rosenberg**, Greenland, Khandekar, Ascensao, Lopez	Gen.	5	
145	Inverse Association of Breast Cancer with the Use of Non-Steroidal Anti-Inflammatory Drugs (NSAIDS): Prospective Results from the Women's Health Initiative	**Harris**, Jackson, Frid, McTiernan, Anderson, White, Ascensao, Chlebowski	OS	5	
152	The Impact of Magnesium Intake on Bone Mass and Risk of Fracture in the Women's Health Initiative Observational Study	**Jackson**, LaCroix, Lewis, Wactawski-Wende, Cauley, Chen, Bassford	OS	5	
155	Changes in Sources of Fat Intake in the Women's Health Initiative Diet Modification Trial	**Patterson**, Kristal, Caan, Van Horn, Simon, Lillington, Snetselaar, Mossavar-Rahmani	CT	5	
20	Correlates of Endogenous Sex Hormone Concentrations in WHI	**McTiernan**, Wactawski-Wende, Chen, Meilahn, LaValluer, Cummings, Hiatt, Baum, Hulka, Wang, McNagny	CT	4	
23	A Comparative Analysis of Predictors of Recruitment for Hispanic and Caucasian Women in the WHI	**Talavera**, Fouad, Howard, Satterfield, Schenken, Simon, Porter, Bonk, Hunt, Wang, Corbie-Smith	Gen.	4	
68	Reliability and Physiologic Correlates of the Physical Activity Questionnaire in the WHI	**White**, Casso, Wang, Stefanick, Siscovick, Cauley, Strickland, Rebar, Rodrigues, Going, Frid	CT	4	

MS ID	Title	Authors	Data Focus	Stage	Reference
80	Insulin Resistance and Weight Change in Postmenopausal Black and White Women	**Howard**, Adams-Campbell, Pasaro, Black, Stevens, Wagenknecht, Rodrigues, Safford, Allen, Snetselaar	Gen.	4	
127	Plasma Homocysteine Levels and Coronary Heart Disease in Women	**Siscovick**, Manson, Trevisan, Wallace, Howard, Burke, Ridker	OS	4	
128	Inflammatory Markers for Coronary Heart Disease in Women	**Pradhan**, Manson, Siscovick, Rossouw, Wallace, Mouton, Jackson, Ridker	OS	4	
129	Thrombotic Markers for Coronary Heart Disease in Women	**LaCroix**, Trevisan, Langer, Lewis, Hsia, Oberman, Kotchen, Ridker	OS	4	
130	Cross-sectional Analysis of Association Between Hormone Replacement Therapy and Thrombotic and Inflammatory Markers for CHD in Women	**Langer**, Manson, LaCroix, Lewis, Hendrix, Rossouw, Pradhan, Ridker	OS	4	
163	Racial/Ethnic Differences in Breast Cancer Incidence Rates	**Chlebowski**, Prentice, Patterson, Paskett, Lane, Hubbell, Rohan, Dolan	OS	4	
164	Leukocyte Count as a Predictor of Cardiovascular Events in Post-Menopausal Women	**Margolis**, Prentice, Greenland, Manson, Assaf, Safford, Howard, Grimm, Bray	OS	4	
18	The Relationship of Dietary Phytoestrogens to Menopausal Symptoms and Major Morbidity in Postmenopausal Women	**San Roman**, Woods, Caggiula, Judd, Brzyski, Liu, Burke, Assaf	CT	3	
45	Socio-demographic Determinants of Folic Acid Intake	**Beresford**, Patterson, Wodarksi, VitolinsKritchevsky	Gen.	3	
47	Is a "Too Low" Fat Diet a Marker of Health or Disease	**Gilligan**, Snetselaar, St. Jeor, Van Horn, Stefanick, Kotchen, Patterson	CT	3	
54	Current Treatment Patterns in Women with Hypercholesterolemia	**Manson**, Freed, Chae	Gen.	3	
56	Psychometric Evaluation of the Urinary Incontinence Scale	**Levine**, Shumaker, Naughton, Kaplan, Bowen	Gen.	3	
90	Passive Smoke Exposure in Childhood and Adulthood and Prevalent Coronary Heart Disease in Women Enrolled in the WHI	**Wagenknecht**, Frishman, Wong, Ockene	OS	3	
118	Association Between Depressive Symptomatology and Physical Activity in Post-menopausal Women	**Rosal**, Ockene, Haan, Brunner, Mouton, Lopez, Perri, Cochrane, Matthews, Jackson	Gen.	3	
121	Quality of Life in Healthy Women and in Breast Cancer Survivors	**Haan**	OS	3	

MS ID	Title	Authors	Data Focus	Stage	Reference
151	History of Estrogen and Oral Contraceptive Use and Cognitive Function: Results from the Women's Health Initiative Memory Study	**Rapp**, Dailey, Gass, Wactawski-Wende, Hendrix, Hogan, Jones, Murphy, Shumaker	WHIMS	3	
153	Metabolic Syndrome and Depression	**Wylie-Rosette**, Cochrane, Perri, Rapp, Rosal	CT	3	
166	Tea Consumption, Bone Mineral Density and Osteoporotic Fractures: Results from the Women's Health Initiative Study	**Chen**, Hakin, Mays, Caan, LaCroix, Ritenbaugh, Robbins, Barad	OS	3	
174	HMG Co-A Reductase Inhibitor (Statin) Use and the Risk of Breast Cancer in the Women's Health Initiative Observational Study	**Cauley**, LaCroix, Chlebowski, Margolis, McTiernan, Vitolins, Furberg, Bauer	OS	3	

Stage
3=Writing group approved
4=Analysis proposed
5=Analysis in progress
6=Analysis completed
7=Draft manuscript
8=Final ms submitted to P&P & PO
9=Final ms approved
10=Submitted
11=In press/published
86=Dropped

Table 9.2
Ancillary Studies

AS #	Title	Study's PI(s)	WHI Investigator	D&A Approval	PO Approval	ID# of Participating Clinics	Study Population	Sample Size	Specimens?	Proposed Study Dates	Funding Status
151	Behavioral Management of Urinary Incontinence in African-American Women	Coralese Ruff	Barbara V. Howard	no		none	OS	150	no		
150	Effect of Airborne Particulate Matter and Other Air Pollutants on the Incidence of Cardiovascular Events in the Women's Health Initiative Observational Study	Joel Kaufman	Garnet Anderson			none	OS	all OS women	no		
149	DNA Repair Genetic Polymorphisms and Breast Cancer Risk	Jennifer Hu	Electra Paskett			none	2001 OS Blood Comp	800/800	yes		
148	Relationship Between Monoclonal Hemopoiesis and other Molecular Abnormalities and the Development of Leukemia in Older Women	Harvey Priesler	Henry Black			none	2001 OS Blood Com	59/177	yes		
147	Gene-gene and gene-environment interactions and breast cancer risk	Charis Eng	Rebecca Jackson			none	2001 OS Blood Com	200/200	yes		
146	A Prospective Study of Pancreatic Cancer Pathogenesis	Charles Fuchs	JoAnn Manson				2001 OS Blood Com	93/279	yes		
145	Pancreatic Cancer	David Whitcomb	Lew Kuller				2001 OS Blood Com		no		
144	Interactions of Polymorphisms in Selected Genes of Thrombogenic & Thrombolytic Systems with Hormone Replacement Therapy as Risk Factors for Atherothrombotic Events in Postmenopausal Women	James Liu		no			2001 OS Blood Com		no		

AS #	Title	Study's PI(s)	WHI Investigator	D&A Approval	PO Approval	ID# of Participating Clinics	Study Population	Sample Size	Specimens?	Proposed Study Dates	Funding Status
143	Treatment of Elevated Cholesterol Among US Postmenopausal Women	Robert Kaplan	Sylvia Smoller			none	2001 OS Blood Com	2250	yes		
142	Thrombosis-related Genes in Population Subgroups Narrowly Defined by Race, Ethnicity, and Place of Birth	Robert Kaplan	Sylvia Smoller			none	2001 OS Blood Com	600	yes		
141	Periodontal Disease and Subclinical Cardiovascular Disease in Post-Menopausal Women	Joan Dorn	Maurizio Trevisan	yes	yes	none	OS	80	no	04/01-06/01	funded
140	Air Pollution and Electrocardiographic Abnormalities	Duanpin Liao	Gerardo Heiss				CT	76285	no		pending
139	Follow-up of Healthy Breast Cancer Survivors in the WHI Observational Study	Electra Paskett	Electra Paskett	yes	yes	none	OS	416	no	8/01-8/02	funded
137	Platelet Polymorphisms as Risk Factors for Myocardial Infarction in Postmenopausal Women and their Interactions with Hormone Replacement Therapy	Paul Bray	Jennifer Hays	yes	yes	none	OS	200-280	yes	01/01/01-6/30/01	
136	The Natural History of Female Pelvic Organ Prolapse	Victoria L Handa	John Robbins	no		none	HRT	377	no	7/1/01-6/1/03	dropped
135	Natural History of Pelvic Organ Prolapse in WHI Women	Ingrid Nygaard	Robert Wallace	yes	yes	none	HRT	400	no	7/01-6/06	funded
134	Serum Estrogen Hormone Metabolites, Hormone Replacement Therapy and the Risk of Breast Cancer	Francesmary Modugno	Lew Kuller	yes	yes		2000 OS Blood Comp	400	yes	1/02-12/02	funded
133	Biochemical and Genetic Markers of Hypertension in White and Black Women	Howard Sesso	JoAnn Manson				2000 OS Blood Comp	800/800	yes		

AS #	Title	Study's PI(s)	WHI Investigator	D&A Approval	PO Approval	ID# of Participating Clinics	Study Population	Sample Size	Specimens?	Proposed Study Dates	Funding Status
132	A Prospective Study of Genetic and Biochemical Predictors of Type 2 Diabetes Mellitus	Simin Liu	JoAnn Manson	yes	yes		2000 OS Blood Comp	3840	yes	12/01-12/04	pending
130	A Randomized Controlled Trial of Fat Reduction, Calcium/Vitamin D Supplementation, Hormone Replacement Therapy, and risk of Proliferative Forms of Benign Breast Disease	Thomas Rohan	S. Wassertheil-Smoller	yes	yes	all	DM, HRT		no	7/01-06/06	funded
129	The Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer	Howard Strickler	S. Wassertheil-Smoller	yes	yes	none	2000 OS Blood Comp	5775	yes	2/02-2/06	funded
128	DNA Mismatch Repair Gene Associated Colorectal, Endometrial and Ovarian Cancer in Postmenopausal Women: a Novel Prospective Population-Based Study	Tom Weber	S. Wassertheil-Smoller	yes	yes	none	2000 OS Blood Comp	6500	yes	12/01-11/06	
127	Impact of Risk Perception on Preventive Health Behaviors, Process of Care and Outcomes Among a Diverse Cohort of Women at High Risk of Ischemic Heart Disease	Janice Barnhart	S. Wassertheil-Smoller	yes	yes	none	OS	350	no	7/01-6/02	pending
126	Molecular and Genetic Determinants of Stroke in the Women's Health Initiative Observational Study	Sylvia Smoller	S. Wassertheil-Smoller	yes	yes	all	OS Umbrella Study	2100	yes	7/01-7/04	resub-mitted 11/01
125	Osteoporosis in Caribbean Hispanic Women	Ellen Cohen	S. Wassertheil-Smoller	yes	yes	none	OS	500	no	7/01-7/05	pending

AS #	Title	Study's PI(s)	WHI Investigator	D&A Approval	PO Approval	ID# of Participating Clinics	Study Population	Sample Size	Specimens?	Proposed Study Dates	Funding Status
124	Sociocultural Influences on Motivation for and Maintenance of Health-Related Dietary Change Among Women	Joylin Namie	Robert Langer	yes	yes	none	DM	90-150	no	6/00-12/00	completed
122	Feasibility Study of Computerized Tailored Dietary Feedback	Karen Glanz	David Curb	yes	yes	none	DM	36	no	3/10/00-9/00	funded
121	Hyperinsulinemia and Ovarian Cancer	Carrie Cottreau	Lew Kuller	yes	yes	none	OS Blood Comp	206	yes	2000-2004	submitted 06/01
120	Epidemiology of Cervical and Lumbar Stenosis	Molly T. Vogt	Lew Kuller	yes	yes	Pittsburgh, Arizona	OS	4000	no	12/00 - 11/04	pending
118	Accuracy of Food Portion Estimation Among Postmenopausal Women	Chrisitine L. Coy	Allen Hubbell	yes	yes	none	DM	191	no	12/1999-4/2000	funded
117	Risk Factors for Dry Eye Syndrome in Postmenopausal Women	Kelley A. Kinney	Rebecca Jackson	yes	yes	none	OS	400	no	9/99-8/02	funded
115	Diabetes In Postmenopausal Women	Barbara V. Howard	Barbara V. Howard	yes	yes	all	OS Umbrella Study	93726	yes		not funded
113	Some Aspects of Mediterranean Diet in Relation to Risk of Chronic Diseases among Postmenopausal Women	Iman Hakim	Tamsen Bassford	yes	yes	none	OS	1000	yes	8/1/99 - 7/31/02	funded
110	Sex steroid hormones and risk of coronary heart disease: A nested case control study	Kathryn Rexrode	JoAnn Manson	yes	yes	none	1998 OS Blood Comp	700	yes	4/1/00 - 3/31/03	funded
108	Gene-environment effects and colorectal cancer	Henry Lin	Rowan Chlebowski			none	2001 OS Blood Comp	800/800	yes		
106	Gene-Diet Interactions in Human Breast Cancer Risk	Jennifer Hu	Electra Paskett			none	1998 OS Blood Comp	800/800	yes		

AS #	Title	Study's PI(s)	WHI Investigator	D&A Approval	PO Approval	ID# of Participating Clinics	Study Population	Sample Size	Specimens?	Proposed Study Dates	Funding Status
105	Carotenoids in Age-Related Eye Disease Study	Julie Mares-Perlman	Catherine Allen	yes	yes	Iowa, Portland, Wisconsin	1998 OS Blood Comp	2880	yes	4/1/00 - 3/31/04	funded
104	Tamoxifen Prevention: Is it acceptable to women at risk?	Joy Melnikow	John Robbins	yes	yes	none	OS	150	no	7/1/99 - 6/30/01	pending
103	Effects of Hormone Replacement Therapy on Cognitive Aging: Women's Health Initiative Study of Cognitive Aging (WHISCA)	Sally Shumaker		yes	yes		HRT	1800	no	4/1/99 - 3/31/05	pending
102	Quality of Life Improvements and Willingness to Pay: An Investigation of Selective Estrogen Receptor Modulators	Mona Eouad	Albert Oberman	yes	yes	none	OS	120	no	10/98 - 9/98	funded
100	Genetic, Biochemical and Behavioral Determinants of Obesity	Jennifer Hays	Jennifer Hays	yes	yes		OS	775	no	through 9/01	funded
99	GENNID Study	Rowan Chlebowski	Rowan Chlebowski	yes	yes	none	ALL	40	yes	12/1/98 - 3/31/00	funded
98	Bone mineral density as a predictor for periodontitis	Jean Wactawski-Wende	Maurizio Trevisan	yes	N/A	none	OS	1000	yes	5/1/99 - 4/30/02	pending
97	Modeling serum markers for cost-effective ovarian cancer screening	Garnet Anderson		yes	yes	none	1998 OS Blood Comp	720	yes	4/1/00 - 3/31/04	funded
95	Work organization, psychological distress, and health among minority older women	Beatriz Rodriguez	David Curb	yes	N/A	none	OS	500	no	till 6/01	funded
93	The Epidemiology of Venous Disease	Michael Criqui	Robert Langer	yes	no		OS	725	no	3/11/98 - 6/30/99	funded
92	Fasting glucose in baseline plasma from all CT participants	Barbara Howard					CT		no	N/A	

AS #	Title	Study's PI(s)	WHI Investigator	D&A Approval	PO Approval	ID# of Participating Clinics	Study Population	Sample Size	Specimens?	Proposed Study Dates	Funding Status
90	Biomarkers and Hip Fracture	Steve Cummings	Steve Cummings	yes	yes	none	OS Umbrella Study	400/400	yes		submitted 10/01
86	A Pilot Study to Determine the Sensitivity of Form 39 to Impaired Executive Control Function (ECF) as measured by the CLOX: an Executive Clock-Drawing Task	M.J. Polk	Robert Schenken	yes	yes	none	HRT	50	no	N/A	funded
84	Apolipoprotein E genotype, ERT use, and fat-soluble vitamin intake: Effects on Cognitive Function in Older Women	Julie E. Dunn	Philip Greenland	yes	yes	none	DM+OS	260	yes	11/98 - 12/03	funded
83	Thrombotic, Inflammatory, and Genetic Markers for Coronary Heart Disease in Postmenopausal Women: A WHI Umbrella Study	Paul Ridker	JoAnn Manson	yes	yes	none	OS Umbrella Study	1300	yes	7/1/99 - 6/30/03	funded
82	Extension of Bone Mineral Density Assessment in WHI Native American Women	Zhao Chen	Cheryl Ritenbaugh	yes	yes	none	OS	200	no	7/1/97 - 6/30/01	completed
78	Community Strategy to Retain Women Enrolled in Research	Mona Fouad	Al Oberman	yes	N/A	none	CT	40	no	7/1/97 - 9/30/97	funded
76	Tailored Messages to Enhance Adherence of Older Women to Dietary Programs for Breast Cancer control	Rowan Chlebowski	Rowan Chlebowski	yes	yes	none	DM	28	no	9/1/97 - 8/13/98	funded
75	Adherence to Dietary Modification in the WHI	Milagros C. Rosal	Judith Ochene	yes	N/A	6 (does not specify which CC's)	DM	480	no	9/1/97 - 8/30/02	funded
74	The Effectiveness of Individual Versus Group Behavioral Strategies to Increase Participants Adherence	Lois Wodarski	Maurizio Trevisan	yes	yes	none	DM	50	no	7/1/97 - 9/30/97	funded

AS #	Title	Study's PI(s)	WHI Investigator	D&A Approval	PO Approval	ID# of Participating Clinics	Study Population	Sample Size	Specimens?	Proposed Study Dates	Funding Status
73	Psychosocial and Cultural Determinants of NIDDM in Latinas	Deborah Parra-Medina	Robert Langer	yes	yes	La Jolla, San Antonio, Tucson	OS	228	no	5/1/97 - 4/30/98	funded
72	Ethnicity, Body Composition, Bone Density and Breast Cancer	Zhao Chen	Cheryl Ritenbaugh	yes	yes	none	OS	800	no	9/1/97 - 8/30/02	funded
70	The Prevalence & Prognostic Importance of Myocardial Ischemia During Daily Life, & its Relationship to Migraine Status:WHI	David Sheps	Gerardo Heiss	yes	yes	10	OS	3200	no	9/1/97 - 8/31/00	funded
68	Coronary artery calcification detected with Ultrafast CT as an indication of CAD in OS participants	Judith Hsia	Judith Hsia	yes	yes	51	OS	782	no	1/1/97 - 12/31/05	funded
67	Prevalence and Natural History of Autoimmune Thyroid Disease is Postmenopausal Women	Marjita Zakarija	Mary Jo O'Sullivan	yes	N/A	51	OS	1040	no	7/97 - 3/31/05	funded
65	Incidence of Benign breast disease in the DM CT - Pilot	Tom Rohan	A. McTiernan	yes	yes	all	DM	200	no	4/1/98 - 6/30/99	completed
63	Development and Evaluation of Eating Style Index	Pam Haines	Gerardo Heiss	yes	yes		OS	800	no	10/1/96 - 6/30/99	funded
62	Prevention of age-related maculopathy in the WHI HRT CT: WHI-SE	Mary Haan	Mary Haan	yes	yes		HRT	3300	no	1/99 - 1/07	funded
61	Longitudinal Assessment of Memory Functioning in the WHI Clinical Trial	Beth Ober	Mary Haan	yes	yes		HRT	110	no	6 year study	funded
60	Fat Intake in Husbands of WHI Dietary Arm Participants	James Shikany	Al Oberman	yes	yes	none	DM Partners		no	12/1/96	funded
57	Hispanic Women's Advocacy and Retention Strategies	Cheryl Ritenbaugh	Cheryl Ritenbaugh	yes	yes	none	OS	120	no	9/1/96 - 8/31/98	funded

AS #	Title	Study's PI(s)	WHI Investigator	D&A Approval	PO Approval	ID# of Participating Clinics	Study Population	Sample Size	Specimens?	Proposed Study Dates	Funding Status
56	Behavioral and psychosocial predictors of dietary change in postmenopausal women	Joan Pleuss	Alice Thomson	yes	yes	none	DM	260	no	9/1/96 - 8/31/98	funded
50	Nutrition Practice Guidelines for Maintaining Low-Fat Dietary Change in Post Menopausal Women	Beth Burrows	Ross Prentice	yes	yes	none	DM	200	no	10/1/96 - 9/30/97	completed
48	Prostate Ca Survey of Spouses of WHI Screened Women	Sylvia Smoller	Sylvia Smoller	yes	yes	none	All	1607	no	2/1/96 - 6/30/96	funded
47	Effect of diet intervention on motivation to make other health-related changes	Langer/Lo	Robert Langer	yes	yes	none	DM	150	no	5/1/96 - 4/30/97	funded
40	Ethnic and age differences in use of Mammography	S. Wassertheil-Smoller	S. Wassertheil-Smoller	yes	yes	none	All	All	no	N/A	funded
39	The Effects of HRT on the Development and Progression of Dementia (WHIMS)	Sally Shumaker	Sally Shumaker	yes	yes	all except #18	HRT	4800	no	5/1/96 - 4/30/02	funded
36	Hormone Replacement Therapy and Changes in Mammographic Density	Gerardo Heiss		yes	yes		HRT	NA	no	1/98 - 12/01	funded
34	Ethnic Differences in Hip Bone Geometry by DXA and QCT	Dorothy Nelson	Susan Hendrix	yes	yes	none	HRT	330	no	12/1/96 - 12/31/02	funded
33	The Association of HRT with Abdominal and Total Body Fat in Postmenopausal Women	Charlotte Mayo	Al Oberman	yes	yes	none	OS	690	no	7/31/95 - 3/31/96	funded
31	Eye Care Use	Robert Kleinstein	Al Oberman	yes	yes	none	OS	300	no	N/A	funded
25	Ankle-Arm Blood Pressure Index Measurement	Kamal Masaki	David Curb	yes	yes	none	OS	2700	no	2/96 - 1/98	funded

AS #	Title	Study's PI(s)	WHI Investigator	D&A Approval	PO Approval	ID# of Participating Clinics	Study Population	Sample Size	Specimens?	Proposed Study Dates	Funding Status
24	Cross-ethnic Comparisons of Skeletal Health of Postmenopausal Women in San Diego County	Diane Schneider	Robert Langer	yes	yes	none	OS	168	no	1/3/95 - 1/2/97	funded
17	Domestic Violence in Older Women	Charles Mouton	Norm Lasser	yes	yes	none	OS	1000	no	10/25/94 - 10/24/96	funded
15	The Relationship between Osteopenia and Periodontitis	Jean Wactawski-Wende	Maurizio Trevisan	yes	yes	none	OS	1300	no	9/16/96 - 9/15/00	funded
14	High Density Lipoprotein Metabolism	Scott Going	Tamsen Bassford	yes	N/A	none	OS	200	no	7/1/94 - 6/30/96	funded
13	Prevalence and Correlates of Lumbar Spinal Stenosis	Molly Vogt	Lew Kuller	yes	N/A	none	CT	150	no	on-going	funded
11	Validation and Exploration of Sleep and Mood Predictors	Daniel Kripke	Robert Langer	yes	N/A	none	OS	600	yes	8/1/95 - 7/31/99	funded
9	An investigation of oral hard tissue status in relation to skeletal bone mineral density measures and osteoporosis	Marjorie Jeffcoat	Al Oberman	yes	N/A	none	OS	650	no	6/1/95 - 5/31/02	funded
5	Explanations for the Development of Fat Distaste	Pamela Green	Deb Bowen	yes	N/A	none	DM	160	no	4/1/95 - 9/30/96	funded